ARTHRITIC FLEXIBILITIES FOR ACCESSING MEDICINES: ANALYSIS OF WTO ACTION REGARDING PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Professor Brook K. Baker*

1. CONTEXT—DEVELOPING COUNTRIES' NEED FOR ACCESS TO ESSENTIAL ON-PATENT MEDICINES FOR TREATING HIV/AIDS AND OTHER DISEASES

As recognized by the U.N. Millennium Development Goals Project, the burden of untreated, but treatable, disease in developing countries is staggering.[1] For example, over 40 million people are living with HIV/AIDS, including nearly 26.6 million in Africa,[2] precipitating a global emergency[3] far overshadowing the SARS scare or the war on terror. Although millions of people living with AIDS in developing countries need immediate access to affordable antiretroviral medicines, ninety-three percent of them, including ninety-eight percent in Africa, are living—and dying—without medicines that have dramatically extended lives in the United States and Europe.[4] AIDS is

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* Northeastern University School of Law, member Health Global Access Project, b.baker@neu.edu.

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1. United Nations Development Programme: Millennium Development Goals ("Goal 6: Combat HIV/AIDS, malaria and other diseases" targets: have halted by 2015 and begun to reverse the incidence and spread of HIV/AIDS, tuberculosis, malaria, and other major diseases), *available at* http://www.undp.org/mdg/ (last visited Apr. 1, 2004).

2. UNAIDS, *AIDS Epidemic Update: December 2003*, 5 (Dec. 1, 2003).

3. World Health Organization (WHO) declared HIV/AIDS a global emergency on September 22, 2003. WHO Fact Sheet 274 (Sept. 2003), *available at* http://www.who.int/mediacentre/factsheets/2003/fs274/en/print.html/html (last visited Apr. 1, 2004). At the Barcelona AIDS Conference in July of 2002, WHO committed to treating 3 million people living with AIDS by the end of 2005. *See* Barcelona HIV Conference website, http://www.actupny.org/reports/bcn/ (last visited Apr. 1, 2004).

4. Nearly six million people living with HIV/AIDS in developing countries need immediate access to affordable medicines or they will die within two years. WHO & UNAIDS, Treating 3 Million by 2005: Making it Happen: The WHO Strategy, 5 (2003), *available at* http:// www.Who.int/3by5/publications/documents/en/Treating3millionby2005.pdf (last visited Apr. 1, 2004). Despite this compelling need, only 400,000 developing world patients are receiving antiretroviral therapy including 100,000 in all of Africa. *Id.* One-third of the developing country total was being treated in Brazil, which provides universal free access to antiretroviral therapy. *See* Jane Galvão, *Access to Antiretroviral Drugs in Brazil*, LANCET, Nov. 5, 2002, *available at* http://image.thelancet.com/extras/01art9038web.pdf (last visited Apr. 1, 2004).

the paradigmatic example, but the issue of access to on-patent essential medicines is not limited to HIV/AIDS or antiretrovirals (ARVs) alone. Poor people in developing countries face a host of infectious diseases, e.g., tuberculosis, malaria, respiratory infections, diarrhea, and chagas disease, for which there is little or no access to medicines, even where cures exist. In addition to infectious diseases, people in developing countries contract many more familiar and equally untreated diseases, including diabetes, asthma, heart disease, cancer, and mental illness.[5] For these diseases, as common in the North as the South, there are a wider array of on-patent medicines, including anti-diabetics, beta-blockers, oncology drugs, and psychiatric drugs, all of which are critically important to the physical and mental health of poor people in developing countries and all of which are priced well beyond affordability.

It is against this backdrop of millions of lives lost needlessly every year that one must judge the world's hesitant and often counter-productive response to the AIDS pandemic and other health problems in developing countries and applaud the growing movement to catalyze a robust trade in low-cost generic medicines. The enormous gap between the need for access to affordable on-patent medicines and its realization reflects a disconnect between the perceived interests of rich countries in the global North, including the highly profitable proprietary pharmaceutical companies[6] that research, develop, and produce patented medicines, and the interests of developing countries in the global South that require life-saving medicines to fight HIV/AIDS and other pandemics that are decimating their poverty-stricken populations. This disconnect occurs at the juncture of national and international intellectual property regimes, especially the World Trade Organization (WTO) Agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPS),[7] national and regional capacities to manufacture and market pharmaceutical products efficiently, and global patterns of income inequality and poverty. While rich, developed countries continue to pursue intellectual property

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5. As stated,

> Noncommunicable diseases such as cardio-vascular diseases, cancer and diabetes are clearly on the increase in African countries. According to the WHO Regional Office for Africa, if this situation is not contained, sixty percent of deaths in the Region by the year 2020 will be caused by NCDs, compared to forty-one percent in 1990.

WHO, *Noncommunicable Diseases: Regional Strategy for 2000-2010* (Aug. 28–Sept. 2, 2000), *available at* http://www.afro.who.int/press/2000/regionalcommittee/rc5006.html (last visited Apr. 4, 2003).

6. Pharmaceuticals have ranked as the most profitable sector in Fortune 500 rankings for the past three decades. Scott Gottlieb, *Drug Companies Maintain "Astounding" Profits*, 324 B.M.J. 1054 (2002).

The top ten U.S. drug makers increased their profits by 32% from $28 billion in 2000 to $37 billion in 2001. *Id.* Together these ten companies report profits of 18.5 cents for every dollar of sales, eight times higher than the median for all Fortune 500 industries. *Id.*

7. Art. 8(1), Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 81 (1994), *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (last visited Feb. 9, 2004) [hereinafter TRIPS Agreement].

protections and trade rules designed to guarantee incentives for innovation by and profits for the proprietary pharmaceutical industry, there is a critical lack of access to medicines essential to counteract disease and to lower the body count of poor people in Africa, Asia, South America, and other developing regions.

Developed countries often promote enhanced intellectual property rights, including those of pharmaceutical producers, as important to development, where the rising tide of import-export economies will rehabilitate failed public health sectors and intellectual property protection will promote local research and development of medicines for diseases primarily found in Africa, South America, and Asia. An alternative solution, pursued by developing countries and treatment activists internationally, is the promotion of efficient generic production by a sufficient number of manufacturers at meaningful economies-of-scale so that medicines can be accessed at lowest cost. To enable trade in generic medicines, developing countries and pro-public health activists have launched a broad-based attack on intellectual property rights that hamstring developing countries' ability to respond proportionately to their urgent crises and more prosaic public health needs by making treatment costs prohibitive.

That generic medicines are cheaper than their brand-name, patent-protected counterparts is undeniable. For example, in February 2001, Cipla of India announced a price heard around the world—a standard package of ARVs for as little as $350/year to NGOs and $600/year to governments in Africa.[8] As more Indian producers entered the market, prices fell even further, and the quality of the drugs was assured through the World Health Organization's (WHO) new pre-qualification program. This fall, a new benchmark price has been established by four generic producers, three Indian and one South African—less than $140/year for the WHO preferred fixed-dose combination medicine.[9] Accordingly, standard quality generics are now available for a penny on the dollar of what the major pharmaceutical companies charge in rich markets.[10]

To enable purchase of assured quality generic drugs, developing countries and activists have also succeeded in convincing donors to establish

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8. Donald G. McNeil Jr., *Indian Company Offers to Supply AIDS Drugs at Low Cost in Africa* N.Y. TIMES, Feb. 7, 2001, *available at* http://www.nytimes.com/2001/02/07/health/07AIDS.html (last visited Feb. 7, 2001).

9. Mark Schoofs, *Clinton Program Would Help Poor Nations Get AIDS Drugs*, WALL ST. J., Oct. 23, 2003.

10. Major pharmaceutical companies have offered price discounts through the WHO co-sponsored Accelerating Access Initiative. However, this Initiative has gotten off to a painfully slow start such that only 36,000 additional patients received medicines between May of 2000 and March of 2002. WHO & UNAIDS Progress Report, *Accelerating Access Initiative: Widening access to care and support for people living with HIV/AIDS* 1-2 (June 2002). Although the figure rose to 150,000 people worldwide by the end of 2003, the conditions that companies impose and the requirement for country-by-country, drug-by-drug negotiations have resulted in a widening gap in access to treatment.

funding structures such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria (Global Fund)[11] and in agitating for greatly enhanced bilateral and multilateral donations so that there are reliable and sustainable reservoirs of purchasing power sufficient to provoke generic entry and to finance purchase of large quantities of medicine. In this regard, the promised tripling of the U.S. response to global AIDS, from $5 billion over five years to $15 billion, may be significant as is the $1 billion commitment to date from the World Bank's Multi-Country HIV/AIDS Program.[12] Although the WHO Commission on Macroeconomics and Health recognizes the centrality of funding for AIDS, tuberculosis, and malaria in the fight against global disease, it advocates spending $34 billion a year by 2007 on *both* general *and* targeted health care programs in developing countries.[13] With this level of funding, the world can begin to reverse the tide of disease, prevent 8 million deaths a year, and generate $360 billion in economic benefits a year.

Developed-country trade policy and pursuit of enhanced intellectual property rights have complicated a viable response to HIV/AIDS and other diseases where patented medicines are too expensive for poor countries to purchase. In place of an energetic global reaction speeding medical care to developing countries, the United States and its European and Japanese allies have enforced a protectionist system of intellectual property protections that frequently keeps low-cost drugs from people in need. This system, designed primarily to preserve drug companies' exclusive access to private sector markets in middle-income developing countries, often forestalls access to dramatically cheaper generic medicines for people in immediate need.

The prime example of this imbalanced sense of priorities occurred in multilateral negotiations that established a uniform system of international intellectual property rights, the WTO TRIPS Agreement. But even after securing a new international standard of patent protection in the GATT negotiations, the United States continued to pursue its goal of heightened intellectual property protections through an ongoing series of trade sanction

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11. *The Global Fund to Fight AIDS, Tuberculosis, and Malaria: FAQ, available at* http://www.globalfundatm.org/en/faq/ (last visited Feb. 10, 2004).

> The concept for an international funding mechanism to fight HIV/AIDS, TB, and malaria began at the Okinawa G8 Summit in July 2000. At the urging of UN Secretary General Kofi Annan and many national leaders, the concept of the Global Fund was unanimously endorsed in June 2001 at the first UN General Assembly Special Session to focus on HIV/AIDS. In July 2001 at its meeting in Genoa, G8 leaders committed US $1.3 billion to the Fund.

Id.

12. The Bush administration has sent mixed messages about whether it will allow purchases of lowest cost generics or preferred proprietary drugs in its new initiative. *See infra* subsection 5.2.

13. Report of the Commission on Macroeconomics and Health, Analysis of the Costs of Scaling Up Priority Health Interventions in Low- and Selected Middle-Income Countries (Appendix 2), *available at* http://www3.who.int/whosis/cmh/cmh_report/e/report.cfm?path=cmh,cmh_report&language=english (last visited Apr. 4, 2004).

threats, its stubborn resistance in WTO negotiations aimed at liberalizing access to medicines, and its pursuit of bilateral and plurilateral negotiations designed to "ratchet" intellectual property protections to an even higher level.[14]

Section 2 of this paper presents a critical analysis of the United States' continued defense of drug company prerogatives and of its multi-forum efforts to achieve even higher levels of intellectual property protection. Concurrently, Section 2 reviews the struggle of developing countries to codify greater recognition of public health perogatives and to engineer increased intellectual property flexibilities, a struggle that reached its high point in Doha, Qatar, on November 14, 2001, when the WTO adopted the Doha Declaration on the TRIPS Agreement and Public Health (the Doha Declaration).[15] Although the Doha Declaration confirmed member states' freedom to issue compulsory licenses and to rely on parallel imports as an alternative source for lower-cost branded medicines, it left open sourcing issues for poor countries that cannot produce medicines efficiently through domestic manufacturers because of insufficient or inefficient pharmaceutical capacity. For these countries, local production is impossible and importation from exporters is increasingly restricted because of a requirement in TRIPS that countries bypassing patent rights for particular medicines must produce predominately for their own domestic markets rather than for export. Thus, Paragraph 6 of the Doha Declaration required a resolution to the production-for-export dilemma by the end of 2002. Despite this deadline, U.S. intransigence resulted in impasse at the end of 2002, necessitating another nine months of negotiation. Finally, on August 30, 2003, WTO members unanimously approved the Decision of 30 August 2003: Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Paragraph 6 Implementation Agreement).[16]

Section 3 of this paper, its major section, summarizes the August 30, 2003 compromise on the Paragraph 6 dilemma and then outlines in detail the multiple options that developing countries have for accessing medicines from willing producers under the TRIPS Agreement, the Doha Declaration, and the new August 30 Paragraph 6 Implementation Agreement. Section 4 of the

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14. Peter Drahos, *Bilateralism in Intellectual Property* (2001), *available at* http://www.oxfam.org.uk/what_we_do/issues/trade/bilateralism_ip.htm (last visited Apr. 1, 2004) (discussing the United States strategy of using bilateral and regional forums to establish higher intellectual property protections which it then pursues in larger regional and international trade negotiations).

15. Declaration on the TRIPS Agreement and Public Health, Ministerial Conference, Fourth Session, Doha, Nov. 9-14 2001, WT/MIN(01)/DEC/2 (Nov. 20, 2001), *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/min01_e.htm (last visited Apr. 4, 2004) [hereinafter Doha Declaration].

16. WTO, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Sept. 1, 2004) WT/L/540, *available at* http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (last visited Apr. 4, 2004) [hereinafter Paragraph 6 Implementation Agreement].

paper then outlines the breadth of legislative reform that developing countries must enact in order to take advantage of the entire range of flexibilities that they now have. Because developing countries with marginal pharmaceutical capacity will still face questions about whether to invest in or subsidize local generic manufacturing or to import essential medicines from abroad, Section 5 provides a brief economic analysis of the prerequisites of efficient generic manufacture and the special importance of economies-of-scale in securing lowest prices. Section 6 discusses procurement policies of the Global Fund and the World Bank and of unilateral initiatives such as the President's Emergency Program for AIDS Relief (PEPFAR) that might impact sourcing decisions.

Arthritic flexibilities achieved in the Doha Declaration and in the Paragraph 6 Implementation Agreement risk being undermined because of the negative impact of bilateral and plurilateral free trade agreements being negotiated by the United States with individual developing countries and with developing regions. Thus, Section 7 of the paper highlights negative aspects of recent U.S. free trade agreements and other trade and intellectual property initiatives. This section recommends that developing countries insist on removing intellectual property provisions affecting medicines from bilateral and plurilateral trade agreements and that the TRIPS Agreement should now be seen as both a floor and a ceiling on such intellectual property rights.[17] Finally, in Section 8, the paper argues first for guaranteed access to proprietary registration data to enable marketing of generic drugs and second that developing country negotiators should not settle for the flawed Paragraph 6 Implementation Agreement during their upcoming negotiation to amend the TRIPS Agreement on a permanent basis. Instead, this paper argues that developing countries should return to a simplified Article 30 solution that puts them on equal footing with large, rich countries that can routinely satisfy their compulsory licensing needs through no-hassle, no-limit domestic production.

17. Although Article 1.1 of TRIPS explicitly allows Member states to "implement in their law more extensive protection than is required by this Agreement," that permission should not end the analysis of whether or not TRIPS should act as a ceiling with respect to the IPR obligations of developing countries.

2. A BRIEF HISTORY OF INTELLECTUAL PROPERTY PROTECTION NEGOTIATIONS: THE TRIPS AGREEMENT, THE DOHA DECLARATION, AND THE PARAGRAPH 6 IMPLEMENTATION AGREEMENT.

2.1: The WTO TRIPS Agreement

The 1994 TRIPS Agreement introduced minimum global standards for protecting and enforcing nearly all forms of intellectual property rights: patents, copyrights, and trade secrets, including those applying to pharmaceuticals.[18] The Agreement was the result of a decade-long movement by a coalition of industries in the United States that united to secure an international standard of intellectual property protections that could be enforced through trade sanctions. Frustrated by the inability of the World Intellectual Property Organization[19] to engineer global standardization and harmonization of IP standards, the pharmaceutical, computer software, publishing, and entertainment industries in the United States cooperated to form their own internal alliances and to lobby business groups to back enhanced intellectual property protections. This strengthened U.S. alliance then worked with industry leaders and networks in other developed countries to motivate the importance of globalizing IP protections. While they were cementing their intercontinental business alliances, these forward thinking industries convinced first the U.S. Trade Representative and then the E.U. and Japanese trade representatives that the General Agreement on Trade Tariffs (GATT)[20] was the forum within which intellectual property protections should be pursued. Although developing countries tried to create a coalition of the unwilling, the United States used its new Section 301 Special Trade List IPR authority to

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18. *See* Peter Drahos & John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy* (2003) (detailed history of the political and strategic genesis of the TRIPS agreement as engineered by U.S. knowledge industries). For a detailed and technical analysis of the background and main policy issues of TRIPS, see *UNCTAC/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development, TRIPS and Development: Resource Book* (2002). For a discussion of the flexibilities available to developing countries with respect to TRIPS-compliant implementation, see Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries, available at* http://www.southcentre.org/publications/publichealth/toc.htm (last visited Apr. 5, 2004). For a discussion of the impact of the TRIPS Agreement and access to medicines, see World Health Organization, *The TRIPS Agreement and Pharmaceuticals: Report of an ASEAN Workshop on the TRIPs Agreement and its Impact on Pharmaceuticals* (2000), *available at* http://www.eldis.org/static/DOC9116.htm (last visited Apr. 5, 2004); Michael Bailey, Ruth Mayne & Dr. Mohga Smith, *Fatal Side Effects: Medicine Patents under the Microscope*, (Feb. 2001), *available at* http://www.oxfam.org.uk/what_we_do/issues/health/fatal_side_effects.htm (last visited Apr. 5, 2004) [hereinafter *Fatal Side Effects*].

19. *See generally About WIPO*, WIPO website, http://www.wipo.int/about-wipo/en/overview.html (last visited Apr. 5, 2004).

20. *See generally* CIESIN Thematic Guides: General Agreement on Tariffs and Trade, *available at* http://www.ciesin.org/TG/PI/TRADE/gatt.html (last visited Apr. 5, 2004).

discipline recalcitrant nations and to split the alliance. Reacting to competition from generic producers, the U.S. and E.U. pharmaceutical industries played a lead role in TRIPS negotiations.[21] At the end of the day, its principal negotiator stated that the industry had achieved all of its aims: controlling the process and the content.[22]

The resulting TRIPS Agreement covers basic principles, standards, and use of patents, enforcement and dispute settlement mechanisms, and multiple other subjects, many of which are tilted in favor of intellectual property owners and against the interests of consumers. Under its key patent provisions, member countries must provide patent protection for a minimum of twenty years from the filing date of a patent application, Article 33, for any invention, including a pharmaceutical product or process, that fulfils the criteria of novelty, inventive step and usefulness, Article 27.1. Although preceding patent-rule pluralism in both the developed and undeveloped world had allowed policy-based discrimination between fields of invention, for example by excluding medicines, Article 27.1 expressly outlawed such discrimination. Similarly, it was no longer permissible to discriminate routinely against imports in favor of locally produced products, thus allowing major pharmaceutical companies to control the *place* of production despite illusory promises to undertake technology transfer.[23] Because of Article 28, the major pharmaceutical producers secured exclusive rights to exclude others from "making, using, offering for sale, selling, or importing" patented pharmaceutical products or products made with a patented process. In addition, Article 39.3 protects undisclosed information (including clinical test data) from "unfair commercial use," a provision that may ultimately be interpreted to impede registration of generic drugs even where patent bars are overcome.[24]

Admittedly, there are important flexibilities in TRIPS, discussed in detail in Section 3, including autonomy under Article 6 to establish international exhaustion rules, which would thereby permit parallel importation,[25] and

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21. *Fatal Side Effects*, *supra* note 18, at 38.

22. "In the words of Edmund Pratt of Pfizer, 'Our combined strength enabled us to establish a global private sector-government network which laid the groundwork for what became TRIPS.'" *Id.*

23. "The protection and enforcement of intellectual property rights should contribute to promotion of technological innovation and to the transfer and dissemination of technology...." Art. 7, TRIPS Agreement, *supra* note 7. Shortly after the adoption TRIPS, a number of developing countries, including Chile and South Africa, lost a significant number of pharmaceutical facilities.

24. For an extended discussion of options concerning appropriate use of undisclosed data, see Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement* (2002). The ability of generic producers to compare generic drugs against previously registered medicines to establish bio-equivalent and comparable bio-availability is crucial to avoid cost-prohibitive, time consuming, and wasteful duplication of clinical trials. *Id.*

25. *See* discussion *infra* subsection 3.2.2.

authority under Article 31 to issue compulsory licenses[26] and under Article 30 to grant limited exceptions to patent holders' right to exclude competition,[27] but the undeniable effect of the TRIPS agreement has been to consolidate the economic power and monopoly privileges of the proprietary drug industry. Given its pre-existing advantage in conducting research and development (96% vs. 4%), the developed world's drug industry secured near absolute competitive advantage over the developing world's via the TRIPS Agreement.[28] This advantage will eventually result in the net transfer of billions of dollars from the impoverished Global South to the affluent Global North.

At the time of its passage, many public health specialists in both developed and developing countries seemed unaware of the looming consequences of a rising tide of patent protection on the treatment of diseases.[29] However, the burgeoning AIDS crisis quickly caught people's attention, especially given the astronomical cost of triple-therapies brought to the market in the mid-1990s. As the developing world confronted the reality of tens of millions of HIV infections and the unaffordability of billions of patent-protected pills, critics questioned the deal that had been struck in the Uruguay Round. Early critics were joined later by more mainstream sources, many of whom offered their own critique of intellectual property fundamentalism, including the prestigious U.K. Commission on Intellectual Property Rights,[30] the UNDP,[31]

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26. *See* discussion *infra* subsections 3.2.3 and 3.2.4.

27. *See* discussion *infra* subsection 3.2.6.

28. WORLD BANK, WORLD DEVELOPMENT INDICATORS 2000, Table 5-12 (2000).

29. There is little doubt that the U.S. and European negotiators were intimately aware of the cost implications of the expanded patent protections—they were negotiating at the bequest and often with the assistance of representatives of the pharmaceutical industry. Likewise, India and Brazil seemed knowledgeable about the future impacts of the agreement, but a divide and conquer strategy by the United States undermined a potential developing country alliance that opposed grafting monopoly-based intellectual protections on top of a multilateral "free trade" agreement. The main tool that the United States used in splitting the incipient alliance was Special 301 Lists and threats of trade sanctions under 19 U.S.C. § 2242 (2003), which was amended in the Omnibus Trade and Competitiveness Act of 1988 to include close surveillance of IPRs. For a history of this use of bilateral threats, see Drahos & Braithwaite, *supra* note 18, at 85-107.

30. Report of the Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (2002), *available at* http://www.iprcommission.org/papers/pdfs/final_report/ciprcoverintrofinal.pdf (last visited Apr. 5, 2004).

31. UNITED NATIONS DEVELOPMENT PROGRAMME, HUMAN DEVELOPMENT REPORT 2001: MAKING NEW TECHNOLOGIES WORK FOR HUMAN DEVELOPMENT (2001), *available at* http://hdr.undp.org/reports/global/2001/en/pdf/completenew.pdf (last visited Apr. 5, 2004).

the World Bank,[32] UNTACD/ICTSD,[33] and even the WTO itself in collaboration with the WHO.[34]

Even after codifying a universally higher standard of patent protections for the pharmaceutical industry in the TRIPS Agreement, the United States continued its existing pro-PhRMA[35] trade policy by threatening developing countries such as Thailand,[36] South Africa,[37] and Brazil[38] with trade sanctions

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32. *Intellectual Property: Balancing Incentives with Competitive Access in* GLOBAL ECONOMIC PROSPECTS, 129-50 (Washington, D.C. 2001), *available at* http://www.worldbank.org/prospects/gep2002/chapt5.pdf (last visited Apr. 6, 2004).

33. UNCTAD-ICTSD, *Intellectual Property Rights: Implications for Development, available at* http://www.ictsd.org/pubs/ictsd_series/iprs/pp/pp_1intro.pdf (last visited June 3, 2004).

34. WTO AGREEMENTS & PUBLIC HEALTH: A JOINT STUDY BY THE WHO AND THE WTO SECRETARIAT (2002).

35. PhRMA (the Pharmaceutical Research and Manufacturers of America) is the trade association for major proprietary drug companies in the United States, PhRMA Homepage, *at* http://www.phrma.org (last visited June 3, 2004). The international pharmaceutical lobby group is called the International Federation of Pharmaceutical Manufacturers Association (IFPMA). IFPMA Homepage, *at* http://www.ifpa.org (last visited June 3, 2004). When referring to PhRMA, this paper is not just referring to the formal trade association but to the international cartel of patent holders that have pursued mutually advantageous intellectual property strategies often in collaboration with U.S. and European trade negotiators.

36. Efforts by the Thai government in 1999-2000 to produce the drug under the compulsory licensing provision of TRIPS, as demanded by Thai NGOs and PLWHAs, failed as the United States government brought intense pressure and made a threat of Special 301 sanctions on Thai exports through its trade arm, the U.S. Trade Representative (USTR), in clear violation of its obligations under the WTO.

> In fact, GPO's attempt at procuring raw materials in December 1999 for DDI from a Japanese company (which is also the main supplier to BMS) also failed because of pressure from BMS. Therefore GPO had to turn to Canadian suppliers who charged twice the price. The BMS case in Thailand is a classic example of the overriding profiteering motives of drug multinationals over access to essential medicines for public health, how companies use patents with minor modifications to establish monopolies and extend the period of patent protection, the bullying trade tactics of the U.S. government and its attempts to preserve the monopoly of its transnational drug companies.

R. Ramachandran, *A Patent War in Thailand,* (Oct. 2003).

37. *See, e.g.*, Omnibus Consolidated and Emergency Supplemental Appropriations Act, Pub. L. No. 105-277, 112 Stat. 2681 (1999):

> [N]one of the funds appropriated under this heading may be available for assistance for the central Government of the Republic of South Africa, until the Secretary of State reports in writing to the appropriate committees of the Congress on the steps being taken by the United State Government to work with the Government of the Republic of South Africa to negotiate the repeal, suspension, or termination of section 15(c) of South Africa's Medicines and Related Substances Control Amendment Act No. 90 of 1997.

According to U.S. State Department documents and statements at the time, "[multiple federal agencies] have been engaged in an assiduous, concerted campaign to persuade the Government of South Africa to modify the provisions of Article 15(C)" that the United States believed violated the TRIPS Agreement. PATRICIA D. SIPLON, AIDS AND THE POLICY STRUGGLE IN THE UNITED STATES 120-21 (2002). For a discussion of early pro-pharma U.S. trade policy in South Africa, see Patrick Bond, *Globalization, Pharmaceutical Pricing and*

because they refused to grant greater TRIPS-plus rights to patent holders and/or because they proposed using TRIPS compliant means to access more affordable medicines. At the same time that the United States was engaged in "a full court press" against South Africa,[39] thirty-nine pharmaceutical plaintiffs sued the Mandela government, challenging new legislation designed to permit parallel importation of medicines a patent holder had sold more cheaply in another country, generic substitution in filling prescriptions of off-patent medicines, and greater price transparency.[40] Fortunately, the trade threats against South Africa, the now infamous pharmaceutical lawsuit, and the WTO complaint against Brazil were all defeated between 1999-2001 by a Southern/Northern alliance that engaged in a coordinated public campaign against U.S./PhRMA policy. As a result of this intense pressure, the Clinton administration eventually reversed some of its more draconian trade threats and promised to pursue a slightly more benign trade policy in sub-Saharan Africa.[41]

2.2: The Doha Declaration

As the pandemic intensified and as treatment activists worldwide demanded a relaxation of the stranglehold patent holders held over life-saving medicines, developing countries collaborated to demand that public health be given a more meaningful role in the interpretation and implementation of the TRIPS Agreement.[42] Thus, in April 2001, Zimbabwe, on behalf of the Africa

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South African Health Policy: Managing Confrontation with U.S. Firms and Politicians, 29 INT'L J. HEALTH SERV. 765, 768 (1999).

38. For a brief history of the U.S. WTO complaint against Brazil, see Ellen t'Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L L. 27, 30-33 (2002).

39. SIPLON, *supra* note 37, at 121.

40. Pharm. Mfrs. Ass'n of S. Africa v. President of the Republic of S. Africa, Case No. 4193/98 (filed Feb. 18, 1998). The lawsuit was unconditionally dismissed in April 2001 following "strong international public outrage." t'Hoen, *supra* note 38, at 31.

41. SIPLON, *supra* note 37, at 123-26. Of particular note is the Clinton Executive Order of May 10, 2000, Exec. Order No. 13,155, 3 C.F.R. 268 (2000), which, in relevant part, reads:

> (a) In administering sections 301-310 of the Trade Act of 1974, the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country, as determined by the President, that regulates HIV/AIDS pharmaceuticals or medical technologies if the law or policy of the country: (1) promotes access to HIV/AIDS pharmaceuticals or medical technologies for affected populations in that country; and (2) provides adequate and effective intellectual property protection consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) referred to in section 101(d)(15) of the Uruguay Round Agreements Act (19 U.S.C. 3511(d)(15)).

42. For a detailed account of this collaboration, 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, 480-90 (2002). Developing countries rejected the theory that differential pricing would meet their needs.

Group, demanded that the TRIPS Council convene a special session on access to medicines. The resulting June 2001 meeting provoked stark positioning by the United States[43] and European Union,[44] who jointly advanced pro-PhRMA positions. However, it also resulted in a strong platform by developing countries that evolved with later submissions to include the following points: (1) developing countries have a broad spectrum of public health concerns, not just HIV/AIDS, and they are particularly concerned about the lack of research on so-called neglected diseases; (2) patents raise prices and thus impede access to medicines; (3) developing countries should be free to use existing TRIPS flexibilities including compulsory licenses and parallel importation without being threatened by developed countries; (4) least developed members need an extension of transitional periods beyond 2006; (5) developing countries need to be able to source generic medicines from exporting countries despite the "predominately for domestic use" rule in Article 31(f) of the TRIPS Agreement, preferably through an Article 30 limited exception; and (6) developing countries need assurances that data protection rules in Article 39.3 would not impede registration of generics.[45]

Although the United States continued to discount the importance of patent protection on either price or access to treatment,[46] to insist on limiting discussion to "emergencies" like HIV/AIDS, malaria, and tuberculosis, and to advocate for restricting parallel importation,[47] the negotiations took a sharp

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43. U.S. Statement at TRIPS Council Meeting, *available at* http://lists.essential.org/pipermail/pharm-policy/2001-June/001175.html (last visited Feb. 10, 2004).

44. Communication from the European Communities and Their Member States, IP/C/W/280 (June 12, 2001).

45. *See* Developing Country Group's Paper, IP/C/W/296 (June 29, 2001); Draft Ministerial Declaration—Proposal from a Group of Developing Countries, IP/C/W/312 (Oct. 4, 2001).

46. In making this argument, the United States relied heavily on an unpublished study subsequently published in the fall of 2001. Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 JAMA 1886, 1888 (2001). Although HIV medicines have not been patented pervasively throughout the developing world, particularly in sub-Saharan Africa, the explanation for this pattern of non-uniform patenting is that smaller and poorer nations do not have markets that warrant the cost of patent applications. Despite incomplete patenting, however, there are multiple antiretroviral patents in those few countries, South Africa, Kenya, and Nigeria, that have meaningful market size and some pharmaceutical capacity. Similarly, there is a pattern whereby some of the most important low-dose, low-cost antiretroviral medicines are patented in countries where the disease is concentrated. Low-cost, front-line antiretroviral therapies involving 3TC, d4T, AZT, Abacavir, and/or Nevirapine are significantly blocked by patents in countries containing sixty-eight percent of HIV positive persons in sub-Saharan Africa. Consumer Project on Technology et al., *Comment on the Attaran/Gillespie-White and PhRMA Surveys of Patents on Antiretroviral drugs in Africa* (Oct. 16, 2001), *available at* http://lists.essential.org/pipermail/ip-health/2001-October/002097.html (last visited Apr. 5, 2004). *See* Sean Flynn, *Legal Strategies for Expanding Access to Medicines*, 17 EMORY INT'L L. REV. 535, 538-39 (2003).

47. Ministerial Declaration pmbl., Contribution from Australia, Canada, Japan, Switzerland and the United States, IP/C/W/313 (Oct. 4, 2001), *available at* http://www.wto.org/english/tratop_e/trips_e/mindecdraft.w313_e.htm (last visited Jan. 31, 2004); *Non-Paper, Contribution from Canada, the Czech Republic, Japan, New Zealand,*

turn in the wake of the anthrax scare in the United States post September 11. Based on a handful of deaths and some anthrax-laden letters delivered to government offices, officials in both the United States and Canada threatened Bayer, the patent owner of ciprofloxacin, a preferred anthrax treatment, with compulsory licenses if Bayer could not supply needed quantities of ciprofloxacin at low cost and in high volumes. Suddenly, the urgency of public health concerns became palpable to U.S. decision-makers. In response, the resolve of the developing world stiffened and prospects for a pro-public health TRIPS accord soared.

Accordingly, on November 14, 2001, WTO members unanimously approved the Doha Declaration. Designed by developing countries to counteract continuing trade threats and a crisis in medical care, the Doha Declaration emphasized the primacy of public health and the right of Member Nations to take measures designed to increase access to affordable medicines. In relevant part, the Doha Declaration states:

Switzerland and the United States, available at http://lists.essential.org/pipermail/ip-health/2001-September/001899.html (last visited Feb. 13, 2004).

1. We recognize the gravity of public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.
5. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.
   (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
   (b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.
   (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
   (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN [Most Favored Nation] and national treatment provisions of Articles 3 and 4.[48]

48. Doha Declaration, *supra* note 15.

In addition to clarifying the preeminence of public health and the importance of access to medicines and confirming key flexibilities within the TRIPS Agreement, the Doha Declaration also promised to resolve the so-called production-for-export problem:

> 6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.[49]

Via paragraph 6, all WTO members recognized that countries with insufficient or inefficient manufacturing capacity would not be able meet their needs for cheaper pharmaceutical products by internal production even when they override patents through the issuance of compulsory licenses.[50] Key transitional time periods in the TRIPS agreement would soon require worldwide protection for pharmaceutical products beginning in 2005, even for countries like India that had previously given patent protection only to pharmaceutical processes.[51] This change in India's patent law would dramatically curtail its current lawful practice of reverse-engineering drugs and then producing them for export. Instead, post-1995 generics produced in any WTO member country (except hypothetically in least developed countries) would ordinarily have to be produced pursuant to compulsory licenses.[52] As previously discussed, Article 31(f) of TRIPS limits production under a compulsory license "predominantly" to the domestic market. This then was

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49. *Id.*

50. Paragraph 6 refers to compulsory licenses, but Article 31 of TRIPS refers to the broader concept of "unauthorized use," which as a practical matter covers both compulsory licenses and non-commercial, governmental use, or "crown use" as it is called in Commonwealth countries.

51. TRIPS Agreement, *supra* note 7, art. 65.4. There is now an even longer transitional period for least developed countries (increased from 2006 to 2016), but the short-term prospect that any of them will become large-scale manufacturers and exporters of pharmaceuticals seems remote. *See id.* art. 66. *See also* Doha Declaration, *supra* note 15, ¶ 7.

52. The problem does not arise simply with respect to medicines newly patented in 2005 or thereafter. TRIPS already has a "mail-box" rule whereby developing countries are obligated to establish mechanisms for receiving, processing, and establishing "priority-in-time" for pharmaceutical patent applications. Furthermore, developing countries have to grant exclusive distribution rights to the patent applicant when certain prescribed conditions were satisfied. TRIPS Agreement, *supra* note 7, art. 70. Thus, the mailbox rule effectively precludes generic manufacturers in developing countries that do not recognize patents on medicines or product patents from producing "copies" of medicines described in pending "mailbox" applications. Stated differently, patent applicants have significant and exclusive market advantages with respect to post-1995 discoveries even before the full adoption of TRIPS in developing countries.

the essence of the production-for-export dilemma—desperate demand but no certain source of future supply.

> 7. We also agree that the least-developed country Members will not be obligated, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these sections until 1 January 2016.[53]

Finally, the Doha Declaration proposed an extension for least-developed country members concerning their obligations to grant and enforce product patents on pharmaceutical products; that and an additional waiver affecting market exclusivity for patent applications held in a transition-period "mailbox" pursuant to Article 70.9 were subsequently voted upon by the General Council.[54] Accordingly, as a matter of TRIPS enforcement, countries could suspend the future operation of their medicines patent and market exclusivity schemes even where they had prematurely and improvidently granted such protections before the expiration of their transition period, January 1, 2006. If they fail to do so by suspending or amending their product patent law, however, patent-holders can continue to file and enforce patents.[55] Moreover, freedom from threat of TRIPS sanctions does not relieve least-developed countries from pre-existing obligations to patent holders who can continue to protect their vested patent rights. Those rights can still be abrogated only via a compulsory license or government use order.

The terms of a fair and expeditious solution for accessing medicines in countries with inadequate domestic capacity were repeatedly advanced by the Africa Group and an affiliated coalition of developing countries[56] and

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53. Doha Declaration, *supra* note 15.

54. The additional ten-year transition period was granted on June 27, 2002. *See Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, IP/C/25 (July 1, 2002), *available at* http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm (last visited Apr. 6, 2004). The waiver on market exclusivity was granted on July 8, 2002. *See Least-Developed Country Members—Obligations under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products*, WT/L/478 (July 12, 2002), *available at* http://www.wto.org/english/tratop_e/trips_e/art70_9_e.htm (last visited Apr. 6, 2004).

55. According to a recent study by the U.K. Commission on Intellectual Property Rights, the majority of least developed countries have prematurely granted patent protections for pharmaceutical products. Phil Thorpe, *Study on the Implementation of the TRIPS Agreement by Developing Countries*, Commission on Intellectual Property Rights, Study Paper 7 (2001).

56. *See* Statement on the Considerations for Paragraph 6 Modalities Delivered by Kenya on Behalf of the African Group, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Malaysia, Sri Lanka and Thailand at the TRIPS Council Meeting on March 5, 2002, IP/C/M/35 (Mar. 22, 2002), *available at* www.law.suffolk.edu/faculty/visiting-past/mpatterson/globaltech/materials/African%20Group%20statement.html (last visited Feb.

NGOs[57]. According to this pro-public health coalition, the production-for-export accord should cover a broad range of diseases and public health needs, so that medicines for multiple debilitating and deadly conditions could be accessed more cheaply. Countries should be able to import a broad range of products including medicines, vaccines, diagnostic tests, and other medical products. Likewise, any country should be able to make use of the Declaration's public health provisions, even though it is undoubtedly true that developing countries had the greatest need. To supply importing countries, any country should be eligible to be an exporter; however, there is an underlying need to fulfill the promise of technology transfer. In addition, onerous diversion rules should not be imposed to address the illusory risk of re-export and sale in rich countries like the United States and Europe that are perfectly capable of reducing or eliminating product diversion on their own. Finally, procedural requirements should be minimized, meaning that a limited exception under Article 30 of the TRIPS Agreement, as endorsed by the WHO[58] and

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26, 2004); Joint Communication from the African Group in the WTO, IP/C/W/351 (June 24, 2002), *available at* http://lists.essential.org/pipermail/ip-health/2002-june/003193.html (last visited Feb. 27, 2004); Communication from Brazil on behalf of Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela, IP/C/W/355 (June 24, 2002), *available at* http://commerce.nic/in/ip_c_w_355.htm (last visited Feb. 27, 2004); South African Non-Paper on Substantive and Procedural Elements of a Report to the General Council under Paragraph 6 of the Declaration on the TRIPS Agreement and Public Health, Job(02)/156 (Nov. 5, 2002), *available at* http://www.cptech.org/ip/wto/p6/southafrica11052002.html (last visited Jan. 30, 2003); Communication from Kenya, the Coordinator of the African Group, IP/C/W/389 (Nov. 14, 2002), *available at* http://essential.org/pipenmail/ip-health/2002-November/003729.html (last visited Feb. 27, 2004).

57. A partial list of international NGOs active in the campaign for access to treatment and for simplified Article 30 procedures includes: Oxfam International; Action Aids Alliance; Consumer Project on Technology US; Health Global Access Project (GAP); Health Action International; Lawyers Collective' HIV/AIDS Unit, India; Medecins sans Frontieres; Thai NGO Coalition on AIDS and Thai Network of People with HIV/AIDS; Third World Network; and Treatment Action Campaign, South Africa.

58. This is the solution expressly endorsed on September 17, 2002, by the World Health Organization:

> [T]he limited exception under Article 30 is the most consistent with this public health principle. This solution will give WTO Members expeditious authorization, as requested by the Doha Declaration, to permit third parties to make, sell and export medicines and other health technologies to address public health needs.

WTO Council for Trips, Statement by the Representative of the WHO, Sept. 17, 2002, *available at* http://www.cptech.org/ip/health/who/who091722002.html (last visited Feb. 27, 2004).

It is also the solution implicitly endorsed by the UK Commission on Intellectual Property Rights, which emphasized the importance of economies-of-scale in attracting generic producers. And, finally, it is the solution temporarily endorsed by the European Parliament to amend its medicines regulation scheme:

> Manufacturing shall be allowed if the medicinal product is intended for export to a third country that has issued a compulsory license for that product, or where a patent is not in force and if there is a request to that effect of the competent public health authorities of that third country.

Amendment 196 to the Directive 2001/83/EC of the European Parliament (since rejected).

many other countries,[59] was vastly superior to the proposed U.S. solution requiring hundreds of product-by-product, country-by-country compulsory licenses in exporting countries. A solution with these terms, articulating definite and enduring rights, would have been a huge step in addressing the crisis of access to affordable medicines in the developing world.

2.3 Unilateral Impasse

After initially agreeing to do so in the Doha Declaration, the United States, for nearly two years, blocked meaningful efforts to liberalize access to generics and in particular blocked an expeditious and efficient solution to the production-for-export dilemma.[60] The extent of the U.S. blocking strategy was epitomized in its first two Paragraph 6 submissions to the TRIPS Council,[61] which proposed the following conditions:

(1) a requirement that export licenses be limited to addressing "grave" or "urgent" public health emergencies, such as HIV/AIDS, TB, and malaria only (a restriction previously defeated in the Doha Declaration);
(2) limits on the types of public health products to be covered by the agreement to pharmaceutical products only;
(3) limits on the sectors which might be supplied by the agreement, specifically excluding the private or "commercial, for-profit sector;"
(4) limits on the importing countries that might benefit from the agreement:
    (a) no application to small market countries that theoretically have technical capacity to produce medicines but insufficient market size to achieve economies-of-scale,
    (b) strict application of the "insufficient manufacturing capacity" standard to exclude countries where production was theoretically possible but otherwise infeasible or impractical,

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59. Developing countries championed an explicit Article 30 solution right up until the fall of 2002, though it is notable that the South African Non-Paper, *supra* note 56, and the Communication from Kenya, the Coordinator of the African Group, *supra* note 56, both fail to mention Article 30 directly.

60. These measures include parallel importation, relaxation of the predominately for domestic use rule in Article 31(f) of the TRIPS Agreement, and use of the limited exception option in Article 30 of the TRIPS Agreement.

61. Communication from the United States, IP/C/W/340 (Mar. 14, 2002); Second Communication from the United States, IP/C/W/358 (July 9, 2002).

(c) income limits that would exclude many developing countries, especially middle-tier countries;

(5) limits on the countries that might export (developing countries only);

(6) a preference for Article 31(f) compulsory licensing solutions in the exporting state that create multiple barriers to implementation including:

(a) prior negotiation on commercially reasonable terms with the patent holder who might impose onerous conditionalities;

(b) costly, burdensome, and protracted individual determinations in administrative or judicial proceedings to grant each license on a case-by-case basis;

(c) dependency on the willingness of a third country to go through such burdensome procedures because of a public health need in a third country,

(d) proof both of a triggering public health need in the affected country and of technical incapacity to produce a particular medicine; and

(e) determination of the level of license compensation in the producing country rather than in the importing country and imposition of a licensing fee even with respect to imports into a no-patent country;

(7) strict anti-diversion guarantees and limitations on re-export, especially to developed countries, but perhaps even regionally between developing countries with comparable public health needs.[62]

According to developing world critics and their allies, each of these conditions violated the letter and spirit of the Doha Declaration and each risked undermining expeditious and efficient responses to public health needs. Although the United States eventually retreated on three conditions,[63] it succeeded in inserting most of them in a "compromise" text agreement

62. Communication from the United States, *supra* note 61; Second Communication from the United States, *supra* note 61.

63. The United States first relaxed its insistence on market segmentation, which theretofore had excluded the for-profit sector. Next, it dropped its insistence on production by developing countries only, but only after this strategy had driven a partial wedge into the developing country coalition, essentially raising questions among some African countries as to whether India and Brazil were pursuing an industrial policy option that would undermine the development of pharmaceutical capacity in Africa. Finally, it agreed to allow more efficient regional trade of generics in WTO-sanctioned regional trading groups, so long as the groups contained at least 50% least developed countries.

prepared by Ambassador Motta, Chairman of the TRIPS Council.[64] However, because it could not impose further agreement with respect to its restrictive view on covered disease,[65] the United States unilaterally rejected the Motta compromise on December 20, 2002,[66] ensuring that a Paragraph 6 solution would not be realized by the end of 2002, as promised.

As expected, developing countries were deeply offended by the U.S. attack on their sovereignty and by its suggestions that only a few diseases should be covered by the paragraph 6 solution. Even though rich countries with ample productive capacity would be able to issue compulsory licenses on any grounds whatsoever pursuant to the baseline flexibilities of Article 31, poorer and smaller countries would have options to address a short list of pandemic diseases and a baker's dozen of tropical diseases for which there were few, if any, medicines.[67] Suddenly, the scales of compulsory licensing were tilted in favor of the United States and Europe, which can produce on-patent medicines domestically should they so decide, and against countries like Malawi, which have to rely on imports. These disfavored countries would, according to Northern demands, have to favor AIDS patients over people with diabetes, or people with malaria over people with asthma. This imbalance

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64. Draft Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, JOB(02)/217 (Dec. 16, 2002), *available at* http://www.cptech.org/ip/wto/p6/wto12162002.html (last visited Feb. 27, 2004).

65. The U.S. position on the scope of disease issue was that the Paragraph 6 solution should only cover grave public health crises associated with HIV/AIDS, malaria, or tuberculosis and other infectious epidemics of comparable scale and gravity. Second Communication from the United States, *supra* note 61.

66. Ambassador Eduardo Pérez Motta of Mexico, who chaired the TRIPS Council, told the General Council of the WTO on December 20, 2002, that "intensive consultations had not resolved differences over the diseases that would be covered by the draft decision on intellectual property and health." WTO Press Release, Press/329, Supachai Disappointed Over Governments' Failure to Agree on Health and Development Issues (Dec. 20, 2002), *at* http://www.wto.org/english/news_e/pres02_e/pr329_e.htm (last visited Feb. 27, 2004).

67. Europe and Japan backed the U.S. attempt to dramatically limit the scope of diseases by jointly proposing a list of tropical diseases, most of which had no effective treatment whatsoever or which had no viable medical treatment still under patent.

> This decision applies to public health problems arising from yellow fever, plague, cholera, meningococcal disease, African trypanosomiasis, dengue, influenza, HIV/AIDS, leishmaniasis, TB, malaria, hepatitis, leptospirosis, pertussis, poliomyelitis, schistosomiasis, typhoid fever, typhus, measles, shigellosis, haemorrhagic fevers, and arbovirues and other epidemics of comparable gravity and scale including those that might arise in the future whether due to natural occurrence, accidental release or deliberate use.

PhRMA/US/Korea/EC/Mexico proposed footnote, *available at* http://www.cptech.org/ip/wto/p6/listofdiseases12202002.html (last visited Feb. 27, 2004). When Europe asked the WHO to broker the list of diseases, ("When requested by a Member, the World Health Organization shall give its advice as to the occurrence in an importing Member, or the likelihood thereof, of any other public health problem," EU Draft Proposal for a Compromise Solution (Jan. 7, 2003)), the WHO politely but firmly declined, (Interview by Vittorio De Filippis and Christian Lossun with German Velasquez, WHO (Jan. 13, 2003), *at* http://www.cptech.org/ip/wto/p6/velasquez01102003.html (last visited Feb. 27, 2004)) sending the negotiators back to the drawing board.

seemed to violate the promise that Doha was a pro-development round and further violated one of the bedrock principles of the WTO free trade system and the TRIPS Agreement, namely that the trading system should not preferentially advantage domestic producers over importing producers.

3. COVERAGE OF THE AUGUST 30 PARAGRAPH 6 IMPLEMENTATION AGREEMENT AND ITS RELATIONSHIP TO PRE-EXISTING AND CONTINUING FLEXIBILITIES IN THE TRIPS AGREEMENT AND THE DOHA DECLARATION

Although the United States and PhRMA continued efforts to influence developing countries to accede to disease restrictions, the pro-public health coalition held firm. In the face of developing country solidarity, the United States and PhRMA eventually relented, but only after insisting that the Paragraph 6 Implementation Agreement be supplemented by the General Council Chairperson's "clarifying" Statement.[68] The exact legal effect of the Chairperson's Statement is uncertain, but it is directly referenced in the underlying Agreement and may well influence interpretation and enforcement of the Agreement at the WTO.[69] Of course, rather than merely clarifying, the Chairperson's Statement wrapped the Paragraph 6 solution with an even tighter tangle of red tape. Nonetheless, developing countries must strive to unravel this tangle in order to access cheaper generic medicines most efficiently.

3.1: Limited Flexibilities in the Paragraph 6 Implementation Agreement and Chairperson's Statement

Although there are many remaining flexibilities for importing generic medicines,[70] neither singly nor collectively do they go far enough to ensure an energetic market in developing countries for generic medicines essential to combat AIDS and other public health problems. In essence, and with the benefit of hindsight, one can see that the United States has engaged in a future-oriented, two-part squeeze play designed to downsize the impact of the Doha Declaration. To counteract this, developing countries must argue for the

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68. *See* WTO News, The General Council Chairperson's Statement (Aug. 30, 2003), *available at* http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm (last visited Apr. 6, 2004) [hereinafter Chairperson's Statement].

69. "This Decision was adopted by the General Council *in light of* a statement read out by the Chairman which can be found in JOB(03)/177." Paragraph 6 Implementation Agreement, *supra* note 16 (emphasis added). At the very least, developed countries will argue that the Chairperson's Statement represents some interpretive guidance with respect to the intention of Member States in adopting the Paragraph 6 Implementation Agreement.

70. *See* subsection 3.2 *infra*.

broadest possible interpretations of the Paragraph 6 Implementation Agreement and resist all efforts to implement it narrowly.[71]

Two structural issues concerning the Paragraph 6 Implementation Agreement should be clarified at the outset. First, the Agreement permits importing by countries where a blocking patent is on file (these countries will need to issue an import license), and by countries with no patent on file, (these countries will not have to issue any license whatsoever).[72] However, the Agreement does require a no-patent importer to use the Agreement's mechanisms when it seeks to import quantities of medicines from the exporting country that would exceed the primarily-for-domestic-use clause of TRIPS Article 31(f). A second structural feature is that the Agreement covers both the compulsory licenses and non-commercial, governmental or "crown" use. Admittedly, most of the express language of the Agreement addresses compulsory licenses, but the Agreement is fundamentally a waiver from the obligations of TRIPS Article 31(b) and (f), which covers all unauthorized uses, including non-commercial, governmental use.[73]

3.1.1 Pharmaceutical products and diseases covered

> 1. For the purposes of this Decision: (a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector 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. . . .[74]

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71. One of the first instances of possible narrowing of the scope of Paragraph 6 implementation was a statement by the Canadian government that it was considering disease limitations in its proposed amendments to its Patent Act. A concerted campaign led by Canadian NGOs has defeated that threat.

72. Paragraph 2(a) of the Decision requires notification of intent to file for a compulsory license when a pharmaceutical product is patented in the imported country, but the necessary implication of this provision is that countries without such patent bars may also make notifications of intent to import an expected quantity of a medicine. *See* Paragraph 6 Implementation Agreement, *supra* note 16.

73. Such governmental use would, in turn, permit production by a state-owned industry, but it would also cover production by a government contractor for public sector provision. An even more sweeping interpretation might allow the government to provision both the public and private sector if it did so without imposing additional mark-ups for non-public-sector uses.

74. *See* Paragraph 6 Implementation Agreement, *supra* note 16.

Developing countries did not obtain the desired clarification that the term "pharmaceutical products" covered vaccines and microbicides, but the definition was expanded to cover "diagnostic kits" needed for the use of another pharmaceutical product. Thus, important blood test technologies are covered. Likewise, including coverage of "active ingredients necessary for the manufacture" of a pharmaceutical product is important in order to access active pharmaceutical ingredients where those ingredients are separately patented.

Developing countries fought hard in the Doha Declaration for the broadest possible disease coverage by the naming of the Declaration, by the unrestricted reference to protecting public health in Paragraph 4,[75] and by the interpretive principles of Paragraph 5(a).[76] Nonetheless, the Paragraph 6 Implementation Agreement cites "public health problems as recognized in paragraph 1 of the Declaration,"[77] rather than paragraph 4, in referencing diseases covered by the Agreement. However, given the tortured nine months of negotiations described in Section 2.3. above, whereby developing countries firmly resisted any efforts to codify disease limitations, the only felicitous interpretation of the phrase "public health problems as recognized in paragraph 1 of the Declaration" is that it covers the broadest range of public health problems, not merely the listed "grave" or pandemic problems.

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75. "We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to *protect public health*. . . . [W]e 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*." Doha Declaration, *supra* note 15 (emphasis added). Paragraph 4 makes no reference to grave public health problems recognized in Paragraph 1, nor does it even make reference to the non-restrictive list of diseases, "HIV/AIDS, tuberculosis, malaria and other epidemics," listed in Paragraph 1. *See id.*

76. *Id.* Paragraph 5 (a) requires that "each provision of the TRIPS Agreement shall be read in light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles." *Id.* Those objectives and principles in TRIPS specifically include Article 8.1 under which "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect *public health*. . . ." TRIPS Agreement, *supra* note 7 (emphasis added).

77. Paragraph 6 Implementation Agreement, *supra* note 16.

3.1.2 "Eligible importing Members" and required notifications

> 1(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification[2] to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system, in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members[78] and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency. . . .[79]
>
> 2. It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

In controlling importing country eligibility, the United States and other developed countries succeeded in imposing four limits on the number of countries that are permitted to import generic medicines to address a public health need using a compulsory license. First, the United States/European Union brokered an absolute agreement with twenty-three relatively rich countries that they would not issue compulsory licenses for importation under any circumstances. Obviously, many of these countries are large enough and have sufficiently capable generic industries to issue a compulsory license for domestic production. But still the United States has succeeded in shrinking the richest part of the international market, essentially engaging in protectionism at a historic level.

Second, the United States/European Union convinced some other, generally smaller or slightly poorer countries (twelve in all), to agree to issue compulsory licenses for import only in order to address national emergencies or other circumstances of extreme urgency.[80] Accordingly, another piece of the potential market for generic medicines was lopped off, including some countries that have no domestic capacity whatsoever. Third, the United States/European Union, forced ten E.U. accession countries to import only on an emergency or urgency basis and to relinquish even this right when they

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

79. *Id.*

80. Chairperson's Statement, *supra* note 68. The countries are Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, and United Arab Emirates. *Id.*

joined the European Union.[81] This will certainly have a devastating impact on the costs of medicines in some very poor Eastern European countries, including some that are facing an escalating HIV/AIDS crisis.

The fourth limitation on the eligibility of importing countries is more subtle and arises with respect to a developing country's right to determine that it lacks sufficient domestic manufacturing capacity in the pharmaceutical sector. Here requirements of proof, opportunities for behind-the-scenes pressure, and the possibility of ad-hoc review impact the potential willingness of developing countries to make use of Paragraph 6 production-for-export mechanisms.

IMPLEMENTATION AGREEMENT PROVISION

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

a. the eligible importing Member(s)[4] has made a notification[2] to the Council for TRIPS, that

. . .

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

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

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

81. *Id.* These countries are Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic, and Slovenia. *Id.*

ANNEX

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

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

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

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

OR

(ii) where the Member has *some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs.* When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.[82]

Pursuant to this provision, least developed countries are automatically eligible importers, regardless of actual capacity. However, other developing countries are eligible only if they have no capacity or insufficient current capacity based on an unspecified form of self-examination. Moreover, they are required to monitor their domestic capacity over time so that when the capacity becomes sufficient, "the system shall no longer apply." Despite the imprecision of the "insufficient capacity" requirement, developing countries were originally pleased that prior notification was not equal to prior "approval by a WTO body" and thus that countries' sovereign decision-making processes were to be honored. Unfortunately, the Chairperson's Statement undermines that reprieve and provides for *ad hoc* review of determinations of insufficient capacity that might deter some countries from using the Paragraph 6 solution.

82. Paragraph 6 Implementation Agreement, *supra* note 16 (emphasis added).

CHAIRPERSON'S STATEMENT

Third, it is important that Members seek to resolve any issues arising from the use and implementation of the Decision expeditiously and amicably:

- 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.*
- In accordance with the normal practice of the TRIPS Council, notifications made under the system shall be brought to the attention of its next meeting.
- *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.*
- *If any Member has concerns that the terms of the Decision have not been fully complied with, the Member may also utilise the good offices of the Director General or Chair of the TRIPS Council, with a view to finding a mutually acceptable solution.*

Fourth, *all information gathered on the implementation of the Decision shall be brought to the attention of the TRIPS Council in its annual review* as set out in paragraph 8 of the Decision.[86]

With the Chairperson's Statement, the United States succeeded in imposing a fourth eligibility barrier that threatens importation for many middle-income developing countries. Basically, the United States has set up an ad hoc notification-and-review process forcing countries that need to import generics because of incapacities in their pharmaceutical sectors to prove, and then defend, their determinations. The standard for proving "insufficient capacity" is terribly uncertain. The United States, in its negotiation positions, has treated insufficient capacity as a technical term addressing theoretical

83. Chairperson's Statement, *supra* note 68 (emphasis added).

physical plant capacity no matter how inefficient or impracticable local production would be. Similarly, the United States does not acknowledge that an industry may be technologically capable, but unable in the short run to produce a needed medicine. Additionally, the United States fails to account for an industry that may be unwilling to apply for a compulsory license because of an overly restricted local market.

On the other hand, developing countries and treatment activists have consistently argued that "insufficient" capacity must be analyzed in pragmatic economic terms to cover situations where local production would be economically inefficient because of inability to reach meaningful economies-of-scale. Access activists essentially argue for an expansive definition of incapacity to mean an inability to produce the medicines quickly, efficiently, and sustainability on terms equal to or better than generic medicines sourced on the international market.[84] Paragraph 6 of the Agreement, where Members acknowledge the importance of reaching economies-of-scale when discussing technology transfer, supports the viability of this interpretation.

Although developing countries have a strong basis to argue that their determinations of insufficient capacity should be given presumptive weight and that their obligations to justify their decisions require only minimum evidence and rationality, the reporting-and-review process could well deter some countries from risking involvement in a damaging and costly WTO dispute resolution process. This prove-it-and-review-it standard does not name countries, but it could have a deterrent effect on middle-income developing countries with some capacity that might otherwise choose to import cheaper generics. To counteract this forced self-exclusion from the Paragraph 6 Implementation Agreement, developing countries will need to be aggressive

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84. The recent threat by Brazil to import three generic anti-retroviral drugs (ARVs) from India (Efavirenz, Lopinavir, and Nelfinavir) is a perfect example of how this fight might play out in the future. *Brazil May Break Patents on Merck & Co., Roche, Abbott Labs AIDS Drugs* (Aug. 21, 2003), *available at* http://lists.essential.org/pipermail/ip-health/2003-August/005140.html (last visited Feb. 27, 2004). It is important to remember, however, that Brazil's threat to import is not subject to Paragraph 6 Implementation Agreement because it involves generics that India can still legally produce. If the Agreement did apply, the United States would certainly argue that Brazil has capacity to manufacture generic ARVs—it has done so in the past, and it has already reverse-engineered the new ARVs. However, Brazil would counter that it cannot make the new generics quickly and perhaps that it cannot do so efficiently in comparison to the lower cost of imported Indian generics.

The United States insisted on a forum for making these kinds of objections and for having the TRIPS Council and even the WTO General Council "review" the operation of the production for export solution. One can imagine the United States complaining that the solution is being abused and that too many countries are seeking import licenses. Developing countries tried to limit this review and argued that the required documentation of incapacity need only be skeletal at best, but now they and generic producers must worry about after-the-fact challenges to import licenses. Once again, one can imagine the reluctance of a generic producer to invest in productive export capacity and to begin to manufacture medicines only to have the import license pulled because of U.S./TRIPS Council review or because of behind-the-scenes U.S. bullying.

in making their incapacity determinations and in resisting after-the-fact micromanagement from the United States or other Member states.

The notification and oversight obligations of least-developed country (LDC) importers differ slightly from those of non-LDC importers with insufficient manufacturing capacity in the pharmaceutical sector. Non-LDC importers must notify the WTO in a timely fashion that they intend to the use the system "in whole or in a limited way" with respect to a particular decision to import a pharmaceutical product.[85] No such obligation is required for a least-developed country Member because they are automatically eligible to use the Agreement's import/export system. However, Paragraph 2(a) of the Agreement requires all importing members to file notifications concerning expected quantities of named medicines and concerning their intent to issue a compulsory license if necessary.[86] Similarly, under Paragraph 2(b)(i), the exporting country may only export to Members who have notified the TRIPS Council of their needs.[87]

3.1.3 Eligible importing "regions"

One of developing countries' victories in the Paragraph 6 negotiations was a provision allowing developing countries to notify the WTO of their collective decision to import medicines and more importantly, the right of a regional trade group to trade generic medicines whether medicines were first produced domestically or imported from a non-regional trade member.

85. Members' flexibility concerning such notification presumably permits countries to opt back in as well as to opt out, though this interpretation is not yet confirmed.

86. *See* Paragraph 6 Implementation Agreement, *supra* note 16.

87. *Id.*

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

> (i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question; . . .[88]

An acknowledged rationale for permitting regional procurement and regional trade in generic medicines was to "harness economies-of-scale." Accordingly, this provision recognizes the value of collaboration to enhance purchasing power and the importance of expanded markets to give incentives for local production. Obviously, this provision will be important in the African context, where regional trading groups could easily involve more than fifty percent least developing countries.

> (ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.[89]

88. *Id.*
89. *Id.*

One of the unfortunate trade-offs in this regional trade provision, however, is developing countries' agreement that a regional patent system is desirable. Of course, there are already two regional patent agreements in Africa.[90] Moreover, it is important for developing countries to try to conserve their administrative resources and to avoid overly duplicative structures between similarly situated members. However, it is by no means certain that harmonization of patent standards will inure to the long-term benefit of developing countries despite the efforts of the World Intellectual Property Organization to achieve the same.[91] This is particularly true since the "technical assistance" provided by developed countries is so often patent-enhancing. The details of patent harmonization, even on an expanded regional basis, should be approached with great caution.

3.1.4. "Eligible exporting Members" and "technology transfer"

> 1.(c) "exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.[92]

The definition of exporting Member is broad enough to include any WTO member. This represents a partial victory for developing countries that did not want to be limited to an unnecessarily restricted list of potential suppliers. Pursuant to this new-found authority, both Canada and the European Commission are pursuing legislation authorizing production-for-export. On the other hand, developing countries had also argued vigorously for enhancements in local capacity to produce medicines and thus had argued for technology transfers and other assistance to help development of that capacity. Gains in this area were meager and contradictory.

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90. Organisation Africaine de la Propriete Intellectuelle (16 members) and African Regional Industrial Property Association (15 members). African Organization of the Intellectual Property homepage, *at* http://www.oapi.wipo.net/fr/about/message.html (last visited Feb. 27, 2004); African Regional Industrial Property Organization homepage, *at* http://www.aripo.wipo.net/membership.html (last visited Feb. 27, 2004).

91. *See, e.g.*, WIPO Working Group on Reform of the Patent Cooperation Treaty, *Options for Future Development of International Search and Examination: Making Greater Use of International Reports*, PCT/R/WG/5/9 (Sept. 19, 2003).

92. Paragraph 6 Implementation Agreement, *supra* note 16.

> 7. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.[93]

Undoubtedly technology transfer is an important issue for developing countries, but it had received little real commitment from developed countries. Indeed most evidence post-TRIPS is that manufacturing capacity in developing countries has been reduced as major producers shut down smaller in-country "finishing factories" that were established to satisfy pre-TRIPS local-working requirements. However, the focus on technology transfer is a double-edged sword. Local production within a country or region can fulfill employment, industrial-policy, and development goals; it can synergistically build technical capacity regarding manufacturing processes; it can ease procurement and distribution problems, contribute to the local tax base, and decrease demand for foreign currency reserves and import financing, though in most instances active ingredients and expertise will still be imported. On the other hand, there may be inefficiencies in local production and therefore real cost disadvantages. Moreover, developing countries should be cautious about over-investment or over-reliance on local production options, especially since so many countries are hoping to become regional suppliers in Africa. Exactly how many generic drug companies in Africa can become cost-effective and price-competitive producers for the region?[94] The Clinton Foundation's ARV agreement with Aspen Pharmacare of South Africa suggests that some African generics can compete with Cipla, Ranbaxy, and Matrix, three Indian producers,[95] but should each African country be wooed into imagining itself as a significant player in the regional market for essential generic medicines?

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93. *Id.*

94. So far Cosmos Pharmaceuticals Ltd. of Kenya, Aspen Pharmacare of South Africa, Farco Mozambique Pty of Mozambique, Bethlehem Pharmaceuticals of Ethiopia, Kimia Farma of Indonesia, Brazilian supported companies in Genin Republic, Ghana, and Nigeria, a Cuban supported firm in Namibia, Shanghai Desano Biopharmaceutical of China, two unidentified companies in Ethiopia, and perhaps others have announced intentions to manufacture generic medicines.

95. Tamar Kahn, Clinton, Aspen to Cut Prices of AIDS Drugs, LIMITED BUS. DAY (S. Afr.), Oct. 24, 2003, at 1.

Answering this question depends in part on the economics of viable generic manufacturing,[96] but developing countries should also be leery of whether the United States and other developed countries will use developing countries' early attempts to establish generic capacity against them. Since the previous discussion of the Paragraph 6 Implementation Agreement already highlighted the fact that the United States has a very narrow technical interpretation of productive capacity, developing countries might soon see themselves shut out, or at least challenged, should they try to switch options and seek imports of other on-patent generic medicines from abroad under the Paragraph 6 accord. In other words, inefficient and thus unsustainable local capacity might haunt developing countries' subsequent resort to alternative, superior sourcing options.

3.1.5 Non-commercial motivation

> 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.[97]

Questions have been raised whether the Chairperson's Statement directly restricts generic exporters' right to make a profit or whether it has alternative meanings.[98] In particular, commentators are concerned about whether an exporting nation like India will be permitted to support the export market by making ready use of the Paragraph 6 Agreement to issue compulsory licenses for export. The U.S. and pharmaceutical interests originally argued (as late as August 2003) that export should be on "humanitarian" grounds only, meaning not for commercial profit.[99] Because of public outcry, however, the United

96. See discussion in sub-section 5, *infra.*

97. Chairperson's Statement, *supra* note 68.

98. Reports in the press have argued that the text is designed to limit drug use in the importing country to public, non-commercial use, that it applies to both locally produced generics and imported ones, and that developing countries should not take measure to promote a domestic pharmaceutical industry. Scott Miller et al., *U.S. Reaches Patent Compromise to Provide Drugs to Poor Nations*, WALL ST. J., Aug. 28, 2003, at A3; Kaiser Daily HIV/AIDS Report, *WTO Deal on Generic Drug Access for Developing Countries Close; Agreement Could Prevent Breakdown of Trade Talks*, Aug. 28, 2003, *available at* http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=19584 (last visited Jan. 31, 2004); TWN Info Service on WTO Issues, *Latest Developments on TRIPS and Health Paragraph 6 and Chair's Statement of Understanding and Analysis of the Text*, Aug. 27, 2003, *available at* http://www.twnside.org.sg/title/twninfo71.htm (last visited Mar. 3, 2004).

99. "In a way, there is a refreshing frankness in the nakedness of the U.S./PhRMA position—'we don't want generic drug companies to make money, we want them to operate on a humanitarian, nonprofit basis while we rake in tens of billions of dollars in profit each and

States eventually agreed to allow the language to be changed from "humanitarian" to that in the Chairperson's Statement: *"[T]he Decision should be used in good faith to protect public health and . . . not as an instrument to pursue industrial or commercial policy objectives."*[100]

Given this language and given PhRMA's historic concern about competition from Indian generics, it is quite likely that the United States will continue to argue that developing countries should not enter the export/compulsory license business if they do so only to develop a competitive pharmaceutical industry and thereby gain comparative advantage in international trade. In light of the U.S.'s concern over diversion, however, it is also possible that the United States is seeking to clarify that the ultimate destination of exported medicines must remain in the Global South and that drugs must not be re-exported through parallel importation or otherwise to the United States and European Union; otherwise, the re-exporter would be pursuing industrial or commercial policy (namely making money on re-export). A final plausible interpretation of the "industrial or commercial policy objective" clause is that the United States is trying to resurrect the private sector limitation that it had originally proposed pre-Doha. A close analysis of the U.S. position suggests, however, that it is primarily interested in deterring the emergence of an even stronger pharmaceutical sector in India.

In rebuttal to the U.S.'s preferred interpretation, public health and access advocates argue that no generic company is going to sell for long on a no-profit basis. For the Paragraph 6 Implementation Agreement to work at all, countries like India, and hopefully China, South Africa, Thailand, and Brazil, will have to become even bigger players in the production and export of generic medicines. However, every time one of these exporting countries issues a compulsory license for export, it would arguably be advancing an industrial and commercial policy of actually enabling a generic manufacturer to provide a sustainable source of supply of standard-quality, low-cost generics to countries that cannot product medicines efficiently on their own. One could wish that the generic industry were altruistic enough to make HIV/AIDS and other medicines on a nonprofit basis, despite investing in productive capacity,

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every year.'" U.S. Latest Conditions on Paragraph 6—Illusory Humanitarian Sales, *available at* http://lists.essential.org/pipermail/ip-health/2003-August/005105.html (last visited Mar. 3, 2004). Confirming this objective, in Montreal, at a July 30 press conference, USTR Zoellick expressly said that the United States does not want the new post-Doha system to become a loophole for creating a commercial export industry. *Zoellick Vows to Work for TRIPS Deal, Lays Out U.S. Conditions,* INSIDE U.S. TRADE, *available at* http://lists.essential.org/pipermail/ip-health/2003-August/005053.html (last visited Feb.27, 2004). Zoellick and PhRMA have consistently charged that the production-for-export system could be "abused" by the generic drug industries in Brazil, China, and most especially India. To limit that "abuse," the U.S./PhRMA team have attempted to limit markets by excluding middle-income developing countries and by excluding medicines for most diseases. Here, they tried to go even further - they would let generic producers export, but only on a hypothetical "humanitarian and non-profit" basis.

100. Chairperson's Statement, *supra* note 68.

fixed-dose combinations, and drug registration. But even the new Clinton Foundation offer of $140/year is premised on some slim margin of profit and a certain quantum of guaranteed purchases.[101]

3.1.6. Conditions on compulsory licenses: quantity terms and royalty rates

> 2.(b) the compulsory license issued by the exporting Member under this Decision shall contain the following conditions:
>
> > i. only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the license and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;
>
> 3. Where a compulsory license is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory license is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.[102]

The Paragraph 6 Implementation Agreement directly limits the quantity of medicines that can be produced for export by requiring that only an amount necessary to meet notified needs of all eligible Members shall be manufactured and that all medicines produced under the export license shall be exported rather than be sold domestically. Fortunately, there is clarity in this provision that supply totals can be aggregated to include authorized demand from regional trade groups. On the other hand, it is extremely unfortunate that the Agreement requires that each export license be for a discrete quantity of a medicine. Using the AIDS pandemic as any example, it will is nearly impossible to predict future need based on expanding capacity and uptake by people testing positive. Thus, it is unavoidable that exporting countries will

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101. Aspen Pharmacare of South Africa, one of the Clinton Foundation's suppliers (the others are Cipla, Ranbaxy, and Matrix, all of India), is already on record that it will earn a "wafer thin" margin of profit. Tamar Kahn, *Clinton Aspen to Cut Price of AIDS Drugs*, BUS. DAY (Cape Town), Oct. 24, 2003, at Health-1, *available at* http://allafrica.com/stories/printable/200310240136.html (last visited Apr. 6, 2004).

102. Paragraph 6 Implementation Agreement, *supra* note 16.

have to issue successive compulsory licenses and/or that the system will need to tolerate quantity amendments to open-ended licenses.

The second required condition on the license is a counter-intuitive obligation that the amount of royalty compensation be set in the exporting country rather than the importing country and that it be set according to the "economic value to the importing Member of the [authorized use]." At first blush, this provision would seem to require exporting Members to rigorously investigate "economic value" in the importing country. The more rational interpretation, however, is to recognize that the value need be only roughly proportional to importing-country GDP, degree of innovation, public versus private research and development costs, prior earnings, remaining life of the patent, purpose of use, and perhaps other factors. An even more rational solution is that the exporting country set a narrow range of presumptive royalty rates in line with common practice.

An added paradox of this remuneration requirement is that it requires a royalty even if the medicine is being produced for a country where the medicine is not patented. In this regard, an importing poor country is worse off under the Paragraph 6 Implementation Agreement than it would have been if it had local capacity to produce medicines. As the ultimate consumer, the importing, no-patent Member will be required to pay the added cost of a license royalty even though there would have been no royalty on locally produced medicines. This is yet another example of how the Paragraph 6 Implementation Agreement is unfairly biased against generic imports.

3.1.7 Product differentiation requirements

> 3. the compulsory license issued by the exporting Member under this Decision shall contain the following conditions:
>
> > ii. products produced under the license shall be clearly identified as being produced under the system set out in this Decision through specific labeling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; . . .[103]

The Paragraph 6 Implementation Agreement contained a compromise on product differentiation. Developed countries and pharmaceutical interests had sought strong differentiation requirements so that there is less temptation to divert nearly identical products from developing countries to more lucrative

103. *Id.*

developed country markets. Developing countries, in contrast, worried about the economic impact of product differentiation and won concessions that such differentiation would not be required if it had "a significant impact on price." The U.S./PhRMA team, however, remained unsatisfied with this compromise and thus insisted on the insertion of the following language in the Chairman's Statement.

> Members recognize that the purpose of the Decision would be defeated if products supplied under this Decision are diverted from the markets for which they are intended. . . . It is the understanding of Members that in general special packaging and/or special colouring or shaping *should not have a significant impact on the price of pharmaceuticals.*
>
> In the past, companies have developed procedures to prevent diversion of products that are, for example, provided through donor programmes. "Best practices" guidelines that draw upon the experiences of companies are attached to this statement for illustrative purposes. Members and producers are encouraged to draw from and use these practices, and to share information on their experiences in preventing diversion.
>
> Attachment: "Best practices" guidelines
>
> Companies have often used special labelling, colouring, shaping, sizing, etc. to differentiate products supplied through donor or discounted pricing programmes from products supplied to other markets. Examples of such measures include the following:
>
> - Bristol Myers Squibb used different markings/imprints on capsules supplied to sub Saharan Africa.
> - Novartis has used different trademark names, one (Riamet®) for an anti-malarial drug provided to developed countries, the other (Coartem®) for the same products supplied to developing countries. Novartis further differentiated the products through distinctive packaging.

- GlaxoSmithKline (GSK) used different outer packaging for its HIV/AIDS medications Combivir, Epivir and Trizivir supplied to developing countries. GSK further differentiated the products by embossing the tablets with a different number than tablets supplied to developed countries, and plans to further differentiate the products by using different colours.
- Merck differentiated its HIV/AIDS antiretroviral medicine CRIXIVAN through special packaging and labelling, i.e., gold-ink printing on the capsule, dark green bottle cap and a bottle label with a light-green background.
- Pfizer used different colouring and shaping for Diflucan pills supplied to South Africa.

Producers have further minimized diversion by entering into contractual arrangements with importers/distributors to ensure delivery of products to the intended markets.

To help ensure use of the most effective anti-diversion measures, Members may share their experiences and practices in preventing diversion either informally or through the TRIPS Council. It would be beneficial for Members and industry to work together to further refine anti-diversion practices and enhance the sharing of information related to identifying, remedying or preventing specific occurrences of diversion.[104]

Any requirement that exporters vary pill size, shape, and color is not cost-free, particularly when moving from round, white tablets or capsules of a standard size, to hexagogonal pills in different sizes and colors.[105] Although it may be sensible to have protections against using a proprietary name or identical packaging (possible trade mark infringements), there is no sense in adding dramatically to costs (and potentially altering bio-equivalence) by changing size, coating, and shape. This unnecessary added cost burden is especially egregious when producers might have to change trade dress, size, and shape for multiple small markets.[106]

Although the Chairperson's Statement adds a presumption that product differentiation does not adversely affect costs, developing countries and

104. Chairperson's Statement, *supra* note 68 (emphasis added). The Statement extended product differentiated rules to cover finished products produced from Paragraph 6 imported active ingredients. "In this regard, the provisions of paragraph 2(b)(ii) apply not only to formulated pharmaceuticals produced and supplied under the system but also to active ingredients produced and supplied under the system and to finished products produced using such active ingredients." *Id.*

105. Rene Shen, *WTO to Close Deal on Medicines Supply, at* http://lists.essential.org/pipermail/ip-health/2003-August/005139.html (last visited Feb. 15, 2004).

106. *Id.*

generic producers should be prepared to argue and document that they do. Even more significantly, if product differentiation affects bio-equivalence, they should argue that the differentiation is "infeasible" as well as uneconomical under the Paragraph 6 Implementation Agreement. Finally, developing countries should select the "best practices" with the least onerous terms, i.e., Novartis.

3.1.8 Other anti-diversion measures

> 4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take *reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation* of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.
>
> 5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.[107]

The Paragraph 6 Implementation Agreement requires importing Members to "take reasonable measures within their means, proportionate to their administrative capacity, and to the risk of trade diversion to prevent re-exportation."[108] Should their efforts to prevent re-exportation be "difficult," then developing countries are obligated to seek mutually agreeable technical and financial cooperation from developed country Members. Although this language imposes no directly enforceable obligations on importing Members with respect to any particular anti-diversion measure, it does suggest that

107. Paragraph 6 Implementation Agreement, *supra* note 16 (emphasis added).
108. *Id.*

pressure will be brought to bear regarding methods designed to reduce product diversion.

In addition to requiring product differentiation and administrative efforts against product diversion, the Paragraph 6 Implementation Agreement also requires a series of notifications from importing and exporting countries and the licensee concerning the identity of the licensed generic producer, the identity and quantities of drugs being produced and exported, and the distinguishing features of the products.[109] Presumably this elaborate system of publicly available notifications is at least partially designed to enable proprietary drug companies to police product diversion.

3.1.9 A procedural morass

The Paragraph 6 notification scheme is elaborate enough, but it builds on the procedural complexity of double-licensing under Article 31 of the TRIPS Agreement. Under the discipline of the combined texts, in order to import medicines in a country where a drug has been patented, the following steps must be followed for a "routine" pro-public health license:

(1) The importing country's potential licensee(s) must seek a voluntary license[110] on commercially reasonable terms for a commercially reasonable period of time from the patent holder.[111] The importing country can ease this requirement by specifying a relatively short time for negotiations, e.g., 30 days, and by specifying presumptively reasonable and unreasonable terms (see discussion on regulation of voluntary licenses, subsection 4.2 *infra*).

(2) Failing that, the potential licensee(s) must apply for a compulsory license from the importing country pursuant to procedures satisfying Article 31 of the TRIPS Agreement, including individual determinations, 31(a),

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109. Paragraph 6 Implementation Agreement, *supra* note 16, Paragraph 2(a), (b)(iii) and (c).

110. Non-exclusive voluntary licenses with relaxed geographical limitations could have a number of advantages. In the best-case scenario, the patent holder could transfer technology and manufacturing know-how to the voluntary licensee, which might produce greater efficiencies and ensure quality. In addition, the patent holder would ordinarily allow its licensee to obtain registration by comparing bio-availability and bio-equivalence of the generic product to confidential data previously filed with the drug registration authority.

111. Prior negotiation is not required under Article 31 (b) and (k) of the TRIPS Agreement where the license is being sought with respect to: (1) an emergency or other matter of extreme urgency (note: HIV/AIDS, TB, and malaria are presumptively such emergencies, Doha Declaration, Paragraph 5(c)); (2) governmental, non-commercial use; and (3) remedies for anti-competitive practices.

limited scope and duration, 31(c) and (g),[112] non-exclusivity and non-assignability, 31(d) and (e), and rights of review, 31(i) and (j).

(3) The importing country must assess its generic industry's capacity and/or willingness to produce the medicine locally, and, if capacity is insufficient, it must notify the WTO of its decision or intention to issue a compulsory license, specify the names and expected quantities of the products needed[113] and explain and justify its rationale concerning insufficient capacity, which rationale is subject to ad hoc challenge and review.[114]

(4) The importing country must license the potential exporter, presumably the one that has already engaged in voluntary license negotiations in the importing country, Article 31(b); this license need not have quantity restriction and could presumptively be issued for the remaining term of the patent so long as it was terminable when the public health need subsided or when domestic manufacturing capacity becomes sufficient.

(5) The exporter may need to seek a voluntary license on commercially reasonable terms for a commercially reasonable period of time in the exporting country, though this requirement is needlessly duplicative and irrational.[115]

(6) The exporter must seek a fully TRIPS-compliant compulsory license from its own government on a single-country, single-product basis, Article 31(a), (c), (d), (e), (g), (i), (j); the export license must be for a specific quantity.

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112. Article 31(c) limits a license to the purpose for which it was authorized; Article 31(g) mandates termination when the circumstances which led to it cease to exist and are unlikely to reoccur; and the Annex to the Implementation Agreement limits it to the period of time that local capacity is insufficient. In the event of ordinary public health licenses, the duration would be at least as long as the public health problem prevails. However, the duration can be shortened further because of increased capacity in the domestic pharmaceutical sector. Paragraph 6 Implementation Agreement, *supra* note 16, Annex, Option ii.

113. "This notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision." *Id.* fn. 5.

114. *Id.* at Paragraph 2(a), Annex; Chairperson's Statement, *supra* note 68.

115. Although this result seems unnecessarily duplicative, especially since the company involved probably first sought a voluntary license in the importing country, the current text of Article 31(b) and the failure of the Paragraph 6 Implementation Agreement to address this second negotiation would seem to require such a ridiculous result.

(7) Compensation by royalty must be individually determined based on economic value in the importing country.[116]

(8) "The exporting Member shall notify the Council of TRIPS of the grant of the license, including the conditions attached to it. The information provided shall include the name and address of the licensee, the product(s) for which the license has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the license. The notification shall also indicate the address of the website [upon which the licensee posts its required notifications]." [117]

(9) If a license is granted, the exporter must investigate pill size, shape, coloring, labeling, and packaging of the patent-holder's product in the importing country and differentiate its new product in material respects, unless to do so is demonstrably too costly or infeasible.

(10) The licensee must post certain required information on a website before shipping detailing: "the quantities being supplied to each destination . . . and the distinguishing features of the product(s)."[118]

(11) The generic producer will need to seek product registration and prove bio-equivalence in the importing country despite the patent holder's effort to prevent "unfair commercial use" of its confidential registration data (TRIPS Article 39.3).

(12) This process must be fulfilled over and over again for each and every drug and for each and every country to which or from which the drug will be exported; moreover, the system may require multiple and successive export licenses for each drug because the precise-quantity requirements.

Shrink the market, increase costs, and add burdensome procedural requirements—is that the simple and efficient solution promised at Doha? The answer is obviously no. The demand-end of the developed-country, post-Doha

116. Despite a requirement of individual determinations, it seems likely that countries could issues guidelines for royalty rates and a presumptive range of royalty rates and that they could shift the burden of persuasion concerning the unreasonableness of the rate to the patent holder.

117. Paragraph 6 Implementation Agreement, *supra* note 16, ¶ 2(c).

118. *Id.* ¶ 2(b)(iii).

strategy was designed to dramatically shrink the potential market for generic drugs and to exclude virtually all markets with meaningful and stable purchasing power. At the supply end, developed countries succeeded in increasing the risks and costs of producing generic medicines for export and in reducing the benefits. In part, the risk factors and reduced benefits for generic producers include shrinking markets. But, in addition, generic producers will be uncertain whether a particular country has properly determined that it lacks sufficient pharmaceutical capacity or whether there is a public health need—decisions that can result in review by the WTO and might also prompt lawsuits by patent-holders such as that previously filed against South Africa.[119] Even more problematic, however, is the procedural labyrinth that stands between a country desperately needing imported generics and a willing manufacturer where the drug is on-patent.

Unfortunately and for reasons are that hard to fathom, developing countries traded their citizens' health for long-promised and indefinitely-delayed reductions in farm export subsidizes and/or for temporary access to developed countries' textile markets (before an even cheaper producer arrives on the scene). Although culpability for the incredible shrinking Doha Declaration rests primarily with the United States (and secondarily with the European Union and Japan), developing countries became co-complicit in enforcing a pharmaceutical embargo, which risks millions of unnecessary deaths.

Despite this critique, both of the Paragraph 6 Implementation Agreement and of developing countries' premature capitulation to developed country power, developing countries held firm on the scope of disease issue, on securing import/re-export rights for regional trade alliances, and on eliminating market exclusivity during extended transitional periods for least developed countries.[120] It is also true that one loophole in the TRIPS agreement, the "predominantly for domestic use rule" was significantly widened as a result of the August 30 accord.

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119. The risk of pharmaceutical company law suits against governments will likely increase if NAFTA-like investment rules are ever engrafted into WTO or other bilateral or plurilateral agreements. These clauses give "investors," meaning foreign companies, the right to take governments to dispute resolution for damages if governmental policy undermines their property rights. Although a full discussion of the investment rule is far beyond the scope of this paper, developing countries should be aware of the future risks of current policy proposals.

120. Paragraph 7 of the Doha Declaration had granted least developed countries an exemption from TRIPS compliance with respect to pharmaceutical products until January 1, 2016. On June 27, 2002, the TRIPS Council voted an addition waiver that would exempt least developed countries from providing five years of market exclusivity to pharmaceutical products under Article 70.9 of the TRIPS Agreement.

3.2 The Full Spectrum of Sourcing Alternatives for Developing Countries Post-Doha

Fortunately, as demonstrated in Chart One below, developing countries retain a great deal of flexibility to use TRIPS-compliant mechanisms to access medicines from abroad, despite the Paragraph 6 Implementation Agreement, though some of these options will narrow in the future. In this regard, it is important to note at the outset that there are now four nestled texts—the original TRIPS Agreement, the subsequent Doha Declaration, the Paragraph 6 Implementation Agreement, and the Chairperson's Statement—which regulate the production and export of generic medicines and their importation. In this regard, it is also important to remember that options within a particular country will also be circumscribed by national legislation and perhaps by its participation in bilateral or regional trade agreements that limit rights it might otherwise have under the four international agreements referenced above.

A threshold problem in assessing sourcing options concerns what might be called the import/export patent thicket.[121] It is extraordinarily difficult to determine the number of patents that might apply to any given pharmaceutical product. These difficulties are intensified in developing countries with antiquated, paper-based patent systems and in patent regimes where patent protections might be forfeited or suspected because of failure to pay an annual patent maintenance fee. The problem is not limited to determining patent status in the importing country—there must be a full search in the exporting Member's patent office as well. Because patents are territorial and because of different filing decisions and filing dates in differing jurisdictions, it is quite likely that the compulsory license in the importing country will differ significantly from that in the exporting country.[122] Thus, a clear area of future reform to make the compulsory license import/export system more rationale and user-friendly is to require patent-holders to create a central facility for listing pharmaceutical patents and/or to require WIPO to perform this function. Fortunately, the World Health Organization has taken a significant step in this direction, with respect to HIV/AIDS by establishing its AIDS Medicines and Diagnostic Service which will develop data base detailing country specific information concerning the patent and registration status of key AIDS medicines. Unfortunately, there is no clear plan at present for comparable data bases for medicines treating other diseases.

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121. *See* Medecins San Frontieres, *Drug Patents Under the Spotlight: Sharing Practical Knowledge about Pharmaceutical Patents* (2003).

122. Carlos Correa, *Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 6 (Draft, Dec. 2003).

Chart One—Flexibilities for Import/Export

EXPORTING COUNTRY (right to export if):	**IMPORTING COUNTRY (right to import if):**
1. Exportation of a drug first sold by the patent holder or with its permission (for parallel importation, no quantity restrictions) 2. Post-patent or off-patent drug (no quantity limits) 3. No patent filed or patent found to be invalid 4. National patent regime did not patent pre-1995 drugs (no retroactivity, no quantity limits) 5. *Compulsory license predominantly for domestic use, Art. 31(f), (49% can be exported)* 6. *Compulsory license for abuse of patent, Art. 31(k), (unlimited export)* 7. *Limited exception to effectuate compulsory license in importing country with no capacity or insufficient market on humanitarian grounds, Art. 30.* 8. *Limited exception to permit export to a no capacity/no patent market on humanitarian grounds, Art.30.* 9. *Paragraph 6 Implementation Agreement, compulsory license with all attendant notifications and limitations, (will be required for post-1995 mailbox drugs and post 2005 new drug inventions; limited quantities.*	1. Parallel importation if country has international exhaustion rule, TRIPS Art. 6; may permit importation of drug produced under compulsory license in exporting country 2. *Regular compulsory license for import, Art. 31 (import allowed pursuant to Art. 27)* 3. *No patent on file (mainly in smaller and poorer countries)* 4. *Paragraph 6 Implementation Agreement compulsory license for import with all attendant notifications and limitations.*

Many different kinds of exporters are currently permitted to sell generics for export where they are not covered by patent protection in the exporting countries. Countries permitted to export, depending on their own national legislation, include:

(1) non-WTO members that can produce and export medicines without WTO complications because of their non-membership, though they might have national legislation protecting patents which would forestall their rights to produce and export generic versions of patented medicines;
(2) least developed countries that do not have to provide patent protection for pharmaceutical products or processes until 2016, although many do so prematurely or under pressure; again national legislation should be amended to permit such production and export;
(3) countries that did not start granting patents on medicines until compelled to do so by the TRIPS Agreement and who can thus make generic versions of pre-1995 drugs legally even without a compulsory license; and
(4) countries like India, who did not have patent production for pharmaceutical "products" in 1994 but only for pharmaceutical "processes" and thus have until 2005 to become fully TRIPS-compliant.

Pursuant to flexibilities and transitional periods in the TRIPS agreement, India can continue to make lawful copies of pre-1995 medicines for export without restriction and will continue to be able to do so indefinitely—the Paragraph 6 Implementation Agreement and the Chairman's Statement arguably have nothing to do with this. The story for post-1995 medicines is more complicated because of a "mailbox rule" in Article 70.9 of the TRIPS Agreement. Under the so-called "mailbox" rule, countries like India are supposed to hold post-1995 patent applications in a "mailbox" pending their TRIPS compliance in 2005. At that time, the patent application would be given priority and the patent, if granted, would extend for the remainder of its twenty-year term. Moreover, even while the patent application is waiting in the "mailbox," the patent holder is supposed to be given five years of marketing exclusivity once the product has been registered for distribution by the country's medicines registration agency assuming it has also been patented and registered by another WTO member. India has just granted its first exclusive marketing rights to a "mailbox" cancer drug, Glivec. Fourteen other pipeline applications have been filed but several, including

Roche's Saquinavir, have been rejected for not fulfilling the required criteria.[123]

Brazilian/Indian Example

In September of 2003, Brazil took the first steps towards issuing a compulsory license to import generic antiretroviral drugs from India. It did so by means of a presidential decree that created a juridical mechanism for generic importation in the case of national emergency or national interest. Through negotiations with Abbott Laboratories, Merck & Co. and Roche, proprietary owners of Lopinavir, Efavirez, and Nelfinavir respectively, Brazil was seeking cheaper sources of supply because it was spending 63% of its $573 million ARV budget on these three medicines alone. On November 19, 2003, only Merck had settled with Brazil after granting a 25% price break on Efavirez (savings $10 million). However, Bristol-Myers Squibb, a fourth company announced a 76% discount on Atazanavir, producing a $60 million annual saving for Brazil.

Admittedly, Brazil has a highly competent generic industry, led by the Far-Manguinhos state laboratory, which has been producing seven non-patent protected ARVs locally. This local production capacity and the credible threat of compulsory licenses have dramatically reduced Brazil's annual costs per patient for antiretroviral therapy. However, even while Brazil evaluates its internal pharmaceutical production capacity and while Far-Manguinhos investigates the development processes of these three newer ARVs, Brazil is seeking to fill a temporary gap in its ability to source these drugs locally.

India is producing the three drugs in question lawfully because its patent system currently protects processes only. Thus, it can export reverse-engineered and differently produced drugs lawfully to any country where there is no patent bar. Because the drugs themselves are not patent protected in India, this entire transaction is not subject to the new Paragraph 6 Implementation Agreement. Instead, India can produce and export any quantity it desires and Brazil can override the existing patents with an ordinary compulsory license.

123. *Novartis Receives EMR for Glivec, available at* http://lists.essential.org/pipermail/ip-health/2003-November/005611.html (last visited Mar. 4, 2004).

3.2.2 Parallel imports

Parallel importation is importation, without the direct consent of the patent-holder, of a product voluntarily and legally marketed in another country by the patent-holder or by another authorized party. The rationale for permitting parallel importing is to promote price competition for patented products by allowing importation of patented products marketed at a lower price in another country by or with the consent of the patent-holder. This indirect competition with oneself is thought to increase the likelihood of fair pricing between countries.

In TRIPS terminology, a patent-holder's right to limit distribution of a product after its first sale has been "exhausted" once the product has been marketed by or with the consent of the patent-holder. Almost all countries have a minimal principle of national exhaustion, permitting resale within a country after a first sale; such resale is necessary to the ordinary movement of products through the wholesale and retail distribution system. In addition to this minimal provision, some countries have adopted an international exhaustion rule, meaning that products can be lawfully imported from a foreign source once the patent holder or its licensee had made a profit (exhausted its rights) via the original sale of the product.

The TRIPS Agreement does not prohibit member countries from adopting the principle of international exhaustion; in fact, it explicitly permits it. That permission starts with Article 6 which states that disputes relating to exhaustion are not subject to the WTO dispute settlement process.[124] Although the United States and European Union argued that Article 27.1 barred parallel importation, despite the Article 6 rule, any doubts on this score were eliminated by the Paragraph 5(d) of the Doha Declaration, which expressly recognized Members' right to elect their own exhaustion rule and thereafter to parallel import.[125]

Under an even more liberal parallel importation rule, a country that recognizes "international exhaustion" might be permitted to import drugs produced under a compulsory license issued in another country, even if there were no compulsory license issued in the importing state. Pursuant to this analysis, parallel importation would be TRIPS-compliant because rights would have been exhausted (or permission for sale would have been granted) by the compulsory licensee.[126] The uncertainty in using this approach, however, is whether the product would be considered to have been "permissibly" placed

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124. TRIPS Agreement, *supra* note 7.

125. *See* Doha Declaration, *supra* note 15.

126. *See generally* Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, Section X.2 (2000), *available at* http://www.southcentre.org/publications/publichealthHoc.htm (last visited Mar. 4, 2004) (advocating this approach).

in the stream of commerce if the product were being produced pursuant to an "involuntary" or compulsory license.

The pharmaceutical industry is highly critical of parallel importation because it limits companies' ability to charge whatever a local market will bear. It also potentially reduces profits in high-price countries, but only if consumers can lawfully obtain cheaper sources of supply with a lower profit margin elsewhere. To allay this risk, most developed countries have imposed significant restrictions on parallel importation of medicines. For example, the United States prohibits the practice completely except for consumer's personal supply of medicines purchased abroad, whereas the European Community permits regional importation only between members of the European Union. In addition, pharmaceutical companies have several private options to circumvent parallel importation rules. The most draconian would be to impose a uniform high price worldwide thereby decreasing affordability in middle-income and low-income nations. Other solutions are subtler. For example, a company could limit its supply to a low-price country to an amount sufficient for internal consumption only. Some patent holders are already pursuing this strategy in Canada where U.S. consumers are beginning to engage in a larger volume of internet sales with Canadian distributors.[127] Alternatively, especially in a price-control jurisdiction, a company could charge two prices, one for domestic consumption and a second for export products.[128]

Although there are many contexts where activists would disapprove of protective anti-parallel pricing practices by multinational pharmaceuticals, prohibitions against parallel export/import probably make the most sense when a company has been "convinced" to make major price concessions to a particular developing country or region, as in the Accelerating Access Initiative.[129] However, a more progressive analysis would not necessarily object to parallel export/import to other developing countries not yet reached by concessionary or discount pricing. Oxfam and others have addressed this dilemma by proposing that there be one parallel import rule for developing countries and another for developed countries. Although developing countries would be free to parallel import from any cheaper branded source, developed countries would not be permitted to parallel import from nations receiving concessionary pricing.[130]

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127. Bernard Simon, *Curtailing Medicines from Canada*, N.Y. TIMES, Nov. 11, 2003, at C1.

128. *See* Medecins Sans Frontieres Access to Essential Medicines Campaign and the Drugs for Neglected Disease Working Group, *Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases, available at* http://www.msf.org/source/access/2001/fatal/fatal.pdf (last visited Feb. 25, 2004) [hereinafter *Fatal Imbalance*].

129. *See generally* World Health Organization, Accelerating Access Initiative, Widening Access to Care and Support for People Living with HIV/AIDS Progress Report (June 2002), *available at* http://www.who.int/hiv/pub/prev_care/aai/en/ (last visited Apr. 6, 2004).

130. *Fatal Imbalance*, *supra* note 128.

3.2.3 "Ordinary" Article 31(b), (f) compulsory licenses—non-predominant quantities

If authorized by local law, Article 31 of TRIPS permits a competent government authority, including a health or patent department, to license the manufacture, sale, and use of an invention to an authorized third-party or government agency without the consent of the patent-holder. Although such licenses could stimulate price-lowering competition and ensure availability of needed medicines, few developing nations, except Malaysia, Mozambique, the Phillipines, and Cameroon, have issued a compulsory license for HIV/ AIDS medicines, though an application is pending in South Africa and licenses have been threatened on several occasions by Brazil. Complicating any such effort is the fact that few developing countries have comprehensive compulsory licensing clauses in their patent legislation. Even as developing countries amend their intellectual property regimes to become TRIPS compliant, many of them are not taking advantage of the TRIPS-compliant compulsory license provisions that exist.

The permissible grounds for compulsory licenses are not fully enumerated or delimited in the TRIPS Agreement, and thus developing nations have significant discretion in selecting health sensitive policies. Permissible grounds for compulsory licensing include public health and the public interest broadly defined, see Article 8, national emergencies, matters of extreme urgency such as epidemics, and public non-commercial use, Article 31(b), and/or to remedy anti-competitive practices, Article 31(k) (discussed further in the following sub-section). Some of these grounds justify expedited governmental action. For example, under Article 31(b), when the government declares an emergency or a matter of extreme urgency, such as the AIDS pandemic, it could seek a compulsory license for itself or for an authorized third party to begin commercial exploitation without first negotiating with the patent holder. Similarly, when the government is seeking a license for public, non-commercial use, the government or its authorized agent is not required to seek prior approval and it can limit the patent-holder's remedies to review of the amount of compensation.[131] Finally, under Article 31(k), if the government acts to redress anti-competitive practices or abuse of patent, it can both reduce the amount of compensation to the patent holder and distribute the product without quantity restrictions outside the domestic market.

Although TRIPS is relatively indifferent about the grounds for issuing a compulsory license, it is relatively strict about the procedures that must be followed in order for an ordinary license to be granted. Except in cases of governmental, non-commercial use, cases arising from anti-competitive practice, or cases involving emergency or extreme urgency, the prospective licensee is ordinarily required to seek a voluntary licensee on commercially

131. TRIPS Agreement, *supra* note 7, art. 42.

reasonable grounds for a reasonable period of time.[132] In addition, as previously stated, the licensee is required to pay adequate compensation.[133] Despite a requirement of case-specific determinations, however, it might be appropriate to set forth factors affecting royalty rates including public expenditures, inventiveness, research and development costs, remaining life of the patent, purpose of use, and other valid factors. Alternatively, countries could specify relatively modest royalties in the range of two to ten percent that have become traditional in the pharmaceutical field.[134]

Even if a compulsory license is granted, the patent-holder retains its underlying intellectual property rights in the patent. The license granted is non-exclusive, meaning the patent-holder and its other licensees can still compete; moreover, the license is non-assignable.[135] More significantly, the license is revocable once the circumstances that led to its granting have ceased to exist, though some consideration must be given to the interests of the licensee who may have invested heavily in order to manufacture the licensed product.[136] This possibility of revocation creates barriers to entry in developing countries even in those rare circumstances where they have sufficient drug manufacturing capacity to produce drugs locally.

One of the most problematic features of the compulsory license regime is that licenses must be issued "predominantly for the supply of the domestic market," except in cases of patent abuse where this limit does not apply.[137] The meaning of this "domestic supply" requirement is inherently unclear as it might mean that "the predominant portion of products produced must be *consumed* domestically" or alternatively that "the license shall be predominantly for the *benefit* of domestic consumption."[138] With the latter interpretation, a country would be justified in exporting a major portion of its production, if such export were necessary in order to have large production runs so as to efficiently supply the domestic market. This is the preferable interpretation of Article 31(f) because it could result in a regional manufacturer being able to supply several small markets in order to achieve cost efficient economies-of-scale. Under any interpretation, however, an

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132. *Id.* art. 31(b).

133. *Id.* art. 31 (h).

134. James Love, Compulsory Licensing: *Models for State Practice in Developing Countries, Access to Medicine and Compliance with WTO TRIPS Accord* paras. 35-42, *available at* http://www.cptech.org/ip/health/cl/recommendedstatepractice.html (last visited Mar. 7, 2004). Canada's proposed royalty rate in its pending patent law amendment is a flat two percent. *Id.*

135. TRIPS Agreement, *supra* note 7, art. 42

136. *Id.* art. 31(c), (g).

137. *Id.* art. 31(f), (k).

138. Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069, 1075-94 (1996).

importing country could utilize a non-Paragraph 6 compulsory license to import the non-predominate portion of an exporting country's generic product.

3.2.4 Article 31(k), competition-based compulsory license

Fortunately, as referenced above, there is a predominately-for-the-domestic-market exception in Article 31(k) where a patent-holder has been found to have anti-competitively abused its patent, by excessive pricing or otherwise, in the producing country. In these circumstances, a generic producer operating under a compulsory license could produce on a large scale for export, most relevantly even where a non-special, non-Paragraph-6 compulsory license had been granted in the importing country. Since TRIPS provides no definition of what might constitute an anti-competitive practice, since Article 1 states that Members should "determine the appropriate method of implementing the provisions of [TRIPS] within their own legal system and practice,"[139] and since Article 8.2 grants Members authority "to prevent abuse of intellectual property rights by rights holders or the resort to practices which unreasonably restrain trade,"[140] it seems clear that individual countries are permitted to develop definitions of anti-competitive behavior so long as they are not transparently TRIPS-nullifying. In this regard, Article 40 directly empowers Member states to address anti-competitive practices in licensing agreements.

By their very nature, drug patents are anti-competitive because they ordinarily enable the patent holder to exclude other manufacturers and vendors. Therefore, although "normal" exploitation of patent rights might not constitute an anti-competitive practice, excessive prices and refusals to license might be held anti-competitive in specific settings, particularly where a pharmaceutical product dominates a therapeutic class, where product substitution is not feasible, and where a supra-competitive price prevails.

Given that many competition schemes are designed to prohibit excessive pricing, it is possible to argue that high prices are unwarranted especially where there is market domination for a particular drug because of the impracticability of product substitution and where the drug is considered an essential commodity. This argument is bolstered when it can be shown that excessive pricing effectively eliminates product availability for a large class of poorer consumers, creating a disproportionate dead-weight loss whereby the vast majority of patients lack affordable access to the medicine. If medicines are not being provided on a reasonably affordable basis, bearing some reasonable relation to the costs of production, then a country could issue a compulsory license under Article 31(k) on the basis of exploitative pricing. Other factors may add to the argument for compulsory licenses, including the

139. TRIPS Agreement, *supra* note 7, art. 1.
140. *Id.* art. 8.2.

fact that the medicines were discovered and developed with public money, such as many AIDS drugs.[141] Another price-related anti-competitive practice might be the now routine practice of patent holders discriminating in prices offered to the public and private sector and the practice of price differentiation among countries. Since price discrimination is frowned upon in many competition schemes, discriminatory pricing might justify the issuance of a license.

An even more promising competition theory is one that combines exploitative pricing and exclusionary practices, e.g., refusals to license generic competitors, where the combined effect creates an access gap for the product. If the patent holder charges a supra-competitive price and if this price is traceable, at least in part to its refusal to license its patent to generic competitors, then this too could be found to be an actionable exclusionary practice. The more radical form of this analysis is that each patent is, in essence, an essential facility and that the patent holder should ordinarily make this patent available to competitors in developing countries once they have obtained approval to market the medicine. An alternative, less radical access-gap theory focuses on the issue of downstream innovation, product improvement, or product combinations. Under this version, the essential facilities doctrine is utilized where a follow-up product cannot be marketed without the approval or a license from one or more patent holder. This doctrine has particular utility with respect to fixed-dose combination medicines[142] and other product improvements. Drug companies rarely make fixed-dose combinations of the most effective antiretroviral therapy combinations because patents on the different medicines are held by different companies and those companies have been unwilling thus far to cross-license medicines with competitors.[143]

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141. James Love, *Public Citizen's Prescription Drug Update—Drug Company Profits* (Oct. 11, 2000) (a thirty-eight percent return on equity, making the pharmaceutical industry the most profitable sector in the U.S. economy).

142. Fixed-dose combinations put three different antiretroviral drugs into a single pill. The WHO endorsed fixed-dose medicines as a crucial component of its ambitious plan to help the world treat three million people living with AIDS by the end of 2005. WHO, *Scaling Up Antiretroviral Therapy in Resource-Limited Settings: Treatment Guidelines for a Public Health Approach*, 9-13, *available at* http://www.who.int/3by5/publications/guidelines/en/arv_guidelines.pdf (last visited Mar. 7, 2004); WHO & UNAIDS, *Treating 3 Million by 2005: Making it Happen: The WHO Strategy, supra* note 4.

143. GlaxoSmithKline does make a fixed dose of its own patented ARVs and one of these, Combivir, is an important therapy. However, Trimune, its three-medicine, fixed-dose combination is no longer a recommended therapy. On January 6, 2004, the FDA approved a combination of Roche's Invirase and Abbott Laboratories' Norvir, where the second acts as a "booster" for the first. Kaiser Daily HIV/AIDS Report, *FDA Approves Antiretroviral Drug Combination of Roche's Invirase, Abbott's Norvir, available at* http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=21549 (last visited Mar. 7, 2004). On May 16, 2004, Bristol-Myers Squibb, Gilead Sciences, Inc., and Merck & Co. Inc. announced talks to co-package and eventually to develop a fixed-dose combination involving Viread, Emtriva, and efavirenz. Lawrence K. Altman, U.S. Speeding Up Approval Steps for AIDS Drugs, N.Y. Times, May 17, 2004, available at http://query.nytimes.com/gst/abstract.html?res=F10F15FB3F5B0C748DDDAC0894DC404482&n=Top%252fNews%252fHealth%252fTopics%252fAIDS (last visited May 27, 2004).

This refusal has had negative public health consequences because it increases patients' pill burden and complicates patient compliance with complex pill-taking schedules. Generic companies, on the other hand, face no such constraint and gladly produce combination medicines when patent rules do not prevent them from doing so.

A final advantage of competition-based compulsory licenses is that they might authorize additional remedies beyond production and sale of a medicine. A competition-based license could, for example, require access to confidential drug registration data, thereby greatly easing the ability of the generic licensee to establish bio-equivalence even where a country had improvidently granted data exclusivity rights.[144] In addition, the patent holder might be forced to transfer secret manufacturing know-how. Both of these expanded intellectual property remedies have been granted in U.S. anti-trust cases involving pharmaceutical companies.[145]

144. According to a recent study, ten percent of seventy developing countries do not permit a second applicant to rely on previously submitted data, while another seventy-five percent have unclear law or no provision on point. Thorpe, *supra* note 55. These numbers are getting worse over time as countries accede to U.S. trade demands. Recent agreements with Chile, Singapore, Jordan, and Central American countries all provide for data exclusivity of at least five years.

145. Colleen Chien, *Cheap Drugs at What Price to Innovation: Does Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L. J. 853 (2003).

SOUTH AFRICAN EXAMPLE

These arguments are no longer theoretical. On October 16, 2003, the South African Competition Commission announced a finding upholding a complaint by the Treatment Action Campaign and others against two pharmaceutical giants, GlaxoSmithKline South Africa and Boehringer Ingelheim, and holding that both companies had charged excessive prices for their patent-protected antiretroviral medicines. The ruling further held that they had unlawfully refused to issue voluntary licenses to generic competitors and that they had thereby unreasonably restricted access to an essential facility preventing production of fixed-dose combination medicines.

Menzi Simelane, Commission at the Competition Commission, said in the Commission's media release that "Our investigation revealed that each of the firms has refused to license their patents to generic manufacturers in return for a reasonable royalty. We believe that this is feasible and that consumers will benefit from cheaper generic versions of the drugs concerned. We will request the Tribunal to make an order authorising any person to exploit the patents to market generic versions of the respondents patented medicines or fixed dose combinations that require these patents, in return for the payment of a reasonable royalty. In addition, we will recommend a penalty of ten percent of the annual turnover of the respondents' ARVs in South Africa for each year that they are found to have violated the Act."

In response to the looming threat of punishing hearings before the Competition Tribunal in South Africa, on December 10, GSK and BI both announced voluntary licensing agreements with the complainants. Under the terms of the settlement agreement, negotiated in the shadow of threatened anti-competitive-practices compulsory licenses, (1) sales will be permitted in public, private, and NGO sectors; (2) there will be an expand geographical scope permitting manufacturers to reach efficient economies of scale so long as they produce the medicines in South Africa; (3) the licenses are open to a reasonable number of producers (four for GSK and three for BI); (4) the licenses permit combination of licenses and production of fixed-dose medicines; and (5) they are be based on modest royalties of five percent only. As of May 2004, final licenses on these terms had still not been consumated.

3.2.5 Legal certainty concerning post-Paragraph 6 Implementation Agreement sourcing flexibilities

Some commentators have been concerned that the Paragraph 6 Implementation Agreement and Chairman's Statement might somehow

compromise or limit flexibilities for accessing imported generics that existed under previous agreements. This is not a credible concern with respect to the four no-patent options first described above, nor even for the Article 31(f) and Article 31(k) options. Paragraph 9 of the Paragraph 6 Implementation Agreement reads as follows:

> This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory license can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.[146]

This paragraph expressly acknowledges all of the no-patent options outlined above. Likewise, it does not directly limit rights under 31(k) or non-predominate amounts under 31(f).

3.2.6 Limited exceptions under Article 30

Paragraph 9 might be interpreted even more liberally to mean that the Paragraph 6 Implementation Agreement does not exclude the possibility of Article 30 production in an exporting country. Although there is no direct recognition of an Article 30 approach, the "Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31,"[147] and Article 30 is still one of those flexibilities.

The text of Article 30 of the TRIPS Agreement certainly evidences enough flexibility to justify limited exceptions designed to address the public health needs of the developing world, including those arising for poor countries that are not able to make effective use of compulsory licenses because they lack meaningful capacity to manufacture medicines locally.

> Members may provide *limited* exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not *unreasonably* conflict with a normal exploitation of the patent and do not *unreasonably* prejudice the legitimate interests of the patent owner, *taking into account the legitimate interest of third parties.*[149]

146. Paragraph 6 Implementation Agreement, *supra* note 16, ¶ 9.
147. *Id.*
148. *Id.* (emphasis added).

As a guiding interpretive principle, it is important to recognize that Article 8 of the TRIPS Agreement authorizes member countries to consider public health and public interests needs when drafting their patent laws "provided that such measures are consistent with the provisions of this Agreement."[149] Similarly, Article 7 provides that intellectual property rights "should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users . . . in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[150] For these two provisions to mean anything, they should mean that member states can balance public health, public interest, and consumer needs in some affirmative way that impacts the unfettered exercise of patent rights. Thus, given the extent of the public health problems in developing countries and given the realities that many developing countries cannot produce medicines locally, it makes sense under public health, trade, and human rights principles to fashion limited exceptions that permit the export-import of generic medicines to those poor nations.

Moreover, the language of Article 30 supports an interpretation that *some* significant impact on patent rights is permissible. For example, the first requirement of Article 30 is that the exception must be limited. Although "limited" does not mean that total abrogation of patents would be permitted, it must mean that some impact is possible, such as the quite significant impact of the "Bolar" exception,[151] which can accelerate approval of generic competition by as much as three years costing the patent holder millions, even billions, of dollars. Similarly, the second and third clauses of Article 30 permit some conflict with the normal exploitation of a patent, though not an "unreasonable conflict," and some prejudice to the legitimate interests of the patent owner, though not "unreasonable prejudice." Lawyers are used to talking about the meaning of what is "unreasonable," but once again the language necessarily suggests that some conflict and some prejudice is permissible—so long as the limited exception does not go too far.

When producing for export only under an Article 30 limited exception, there is no real curtailment of the patent holder's rights in the consuming country. If that country had manufacturing capacity, it could produce medicines own its own. Since it does not, a limited exception simply gives no-capacity countries a legal source of off-site manufacture, leveling their playing

149. TRIPS Agreement, *supra* note 7, art. 8.

150. *Id.* art. 7.

151. *WTO, Canada—Patent Protection of Pharmaceutical Products, Report of the Panel*, WT/DS114/R (March 17, 2000), *available at* http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf (last visited Mar. 7, 2004) [hereinafter Generic Medicines]. In Generic Medicines, the panel found that manufacture before patent expiration so as to register a medicine, the so-called "Bolar" exception was lawful, but that a six-month stock-piling rule was unlawful. In particular to the point under discussion, Generic Medicines found that any exception which resulted in a substantial curtailment of [any exclusionary right] cannot be considered a limited exception. *Id.* ¶ 7.44.

field vis-à-vis countries with productive capacity. If the medicine were on-patent in the importing country, the importer would pay a previously determined royalty fee. Alternatively, if the medicine were off-patent in the importing country, then a royalty imposed in the exporting country would not unreasonably burden its consumers.

Fortunately, the language of Article 30 does not suggest that only the patent holder's rights be considered; instead, it requires that the exception be judged "taking account of the legitimate interests of third parties"[152] including presumably millions of poor people living with HIV/AIDS and other treatable diseases. There is no geographical scope given about "third parties" who count, and thus the legitimate interests of third parties living in developing countries weigh heavily. This last proviso strongly suggests that Article 30 incorporates a principle of proportionality such that if the public health interests of third parties are substantial, then a more significant limitation on patent rights is permissible. In the real world, if these "third parties" in developing countries do not get the lowest-price, assured-quality generics available, they *will* die.

3.2.7 The Paragraph 6 Implementation Agreement

The real difficulties of the Paragraph 6 Implementation Agreement and Chairman's Statement concern post-1995 discoveries and arise much more broadly in 2005 when no one but non-WTO members, least developed countries, and/or companies in WTO member countries that have issued compulsory licenses will be able to manufacture and export a patented medicine. It is at this time that countries like India will have to become fully TRIPS compliant and will have to provide patent protection for post-1995 pipeline/mailbox patent applications and for all post 2005 discoveries if a patent has been filed and granted.

The Implementation Agreement also applies to countries where a medicine is currently on patent and where it seeks to export more than forty-nine percent of the product under a non-competition-remedy compulsory license. Thus, for example, were Nigeria to seek becoming a regional producer and exporter in Southern Africa, it would need to issue Implementation Agreement-compliant compulsory licenses. On the more immediate horizon, Canada would need to do so also if it succeeds in amending its patent legislation as promised.

152. TRIPS Agreement, *supra* note 7, art. 30.

THE CANADIAN EXAMPLE—LEGISLATIVE REFORM

On Thursday, November 6, 2003, the Canadian government introduced a bill that would amend its Patent Act to provide for the issuance of compulsory licenses that would allow Canadian generic manufactures to make and export generic versions of patented pharmaceutical products to developing countries lacking their own manufacturing capacity. Canadian NGOs and the UN Special Envoy on HIV/AIDS in Africa, Stephen Lewis, had urged the government to take this initiative following the August 30 Paragraph 6 Implementation Agreement. Canadian civil society organizations were reportedly pleased that the proposed bill did not authorize compulsory licensing of pharmaceuticals only to treat specific diseases or to address only "emergencies" or other circumstances of extreme urgency as initially reported. However civil society organizations identified some serious flaws in the bill as introduced.

(1) *Provisions permitting patent-holders a right of first refusal to block export licenses.* The original bill included provisions that gave the company holding the Canadian patent on a pharmaceutical product the right of first refusal to take over contracts negotiated by generic pharmaceutical manufacturers with developing country governments or other authorized importers. In order to do so, the patent-holding company would have 30 days to meet the terms of the contract negotiated between the Canadian generic producer and the developing country purchaser. Under the Bill as initially drafted, if the patent-holder took over the contract the patent holder would be relieved from any obligation to negotiate the terms of a voluntary license for the generic manufacturer to make and export the product and the Commissioner of Patents would be prohibited from issuing a compulsory license to the generic company. Under such a legislative scheme, generic manufacturers might quickly lose incentive to negotiate export contracts in the first place. Instead the patent-holder would be able to repeatedly block the generic manufacturer from obtaining the export license needed to make the product and fulfill the contract.

(2) *Limited list of pharmaceutical products.* The original bill listed pharmaceutical products for which a compulsory license might be obtained, limited to patented medicines on the WHO Model List of Essential Medicines. The bill also contemplated that the Canadian Cabinet could authorize the addition (or removal) of any other "patented product that may be used to address public health problems." Given the protracted battle over disease limitations post-Doha, a limited list of products represents a step backward and is certainly not required by the Paragraph 6 Implementation Agreement.

(3) *Denial of benefit to developing countries that are not WTO members.* Under the initial bill, all countries recognized as "least-developed countries" could benefit from the export of generic pharmaceutical products as could developing country WTO members. However, developing countries that did not belong to the WTO were unable to benefit from the possibility of importing generic pharmaceuticals from Canada.

Because of opposition from AIDS activists and other opinion leaders, the original bill was substantially improved before its enactment on May 14, 2004. The right of first refusal was removed, but unfortunately replaced with a still onerous clause restricting "commercial motivation" and placing caps on prices and cost-markups for Canadian produced generics. The exclusion of non-WTO members was also removed, but here too an unnecessary restriction was engrafted, one requiring the importing country to declare an emergency. Nonetheless, although the enacted law has not yet been proclaimed into force pending promulgation of implementing regulations, Canada has become the first nation to pass Paragraph 6 Implementation Agreement legislation to permit export of medicines to countries without meaningful productive capacity.

4. Legislative Reform in Importing and Exporting Countries [153]

In order for any exportation of on-patent medicines to be lawful, whether pursuant to exhaustion rules, an Article 31(f) or 31(k) compulsory license, or an Article 30 limited exception, there must be enabling legislation in the exporting country permitting such exportation. Likewise, there must also be provisions for issuance of import compulsory licenses in importing nations where medicines are under patent. Accordingly, in order to maximize their future flexibilities, most countries should enact legislation with respect being both an importer and an exporter of generic medicines.

A previous review of developed country patent laws reveals that few of them have incorporated pro-public health flexibilities into their patent schemes. For example, only thirteen countries have adopted legislation permitting issuance of voluntary licenses to address public health emergencies, only eleven to remedy anti-competitive practices, and only four for failure to license.[154] Moreover, another constellation of developing and least developed

153. *See* Canadian HIV/AIDS Legal Network, *Update: Amendment to Canada's Patent Act to Authorize Export of Generic Pharmaceuticals*, *available at* www.aidslaw.ca/Main content/issues/cts/patent-amend/Patent ActAmendment_Update.pdf (last visited Feb. 12, 2004).

154. Carlos Correa, WHO Health Economics and Drugs, EDM Series No. 12, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, WHO/EDM/PAR/2002.3, *available at* http://www.who.int/medicines/library/per/who-edm-par-2002-3/doha-

countries has prematurely adopted TRIPS compliant legislation and in some cases TRIPS-plus legislation. Thus, in order to secure the hard fought gains in the Doha Declaration and the Paragraph 6 Implementation Agreement, developing countries must quickly operationalize all the flexibilities they have achieved by amending national legislation as outlined in Chart Two below.

implications.doc (last visited Mar. 7, 2004).

CHART TWO LEGISLATIVE REFORM

Legislative Reform in Importing Country	**Legislative Reform in Exporting Country**
1. Authority to grant compulsory licenses on all permissible grounds: *a. For emergencies and other matters of extreme urgency without prior notification (TRIPS Art. 31(b)); would be wise to designate HIV/AIDS, TB, and malaria as public health matters of extreme urgency not subject to emergency declaration standards, constitutional or legislative (Doha Declaration ¶ 5(c));* *b. For governmental non-commercial use without prior notification (TRIPS Art. 31(b);* *c. On other public health grounds for any diseases and medical conditions requiring access to more affordable pharmaceutical products (TRIPS Art. 31(b), Doha Declaration ¶ 5(b))* *d. To remedy anti-competitive practices and therefore to be able to export to other countries (TRIPS Art. 31(k), Art. 40):* *i. Abusive or excessive pricing leading to a gap in access (S.A. Comp. Comm.);* *ii. Refusal to issue voluntary licenses (S.A. Comp. Comm.);* *iii. Essential technology or essential facilities doctrine especially important with respect to sourcing fixed-dose combination medicines (S.A. Comp Comm.)* *iv. Any and all other anti-competitive practices;* *e. Stipulation that all such licenses can be satisfied by local production and/or import (TRIPS Art. 27.1)* *f. Special compulsory licenses for import when country determines it lacks capacity to manufacture efficiently or timely domestically (Para. 6 Implementation Agreement);* *g. Ability to register generics produced under a compulsory license via comparison to confidential data (TRIPS Art. 39.3);* *h. Limits on patent-holders' rights of appeal and preclusion of injunctive relief.* *2. International exhaustion regime allowing parallel importation (TRIPS Art. 6, Doha Declaration ¶ 5(d)).* *3. Ability to export regionally if part of a regional trade agreement (Paragraph 6 Implementation Agreement ¶ 6(i)).*	*1. Authority to grant regular compulsory license on all permissible grounds (emergencies, governmental/non-commercial use, public health, and to remedy anti-competitive practices) (TRIPS Art. 31(b), 31(k), Doha Declaration ¶ 5(b) and (c);* *2. Authority to export non-predominate quantities pursuant to a regular compulsory license (TRIPS Art. 31(f)) and authority to export unlimited quantities in the event of practices found anti-competitive (TRIPS Art. 31(k), see 1.d opposite, grounds for issuing licenses for anti-competitive practices).* *3. Authority to grant compulsory licenses on the basis of notification by a member developing country to the TRIPS Council pursuant to the Paragraph 6 Implementation Agreement;* *a. Should allow simplified procedures;* *b. Should allow joint consideration of concurrent licenses on multiple drugs and for multiple importers;* *c. Must require notification, procedures and limitations of the Paragraph 6 Implementation Agreement (and perhaps the Chairperson's Statement);* *d. Should limit rights of appeal and preclude injunctive relief by patent holders;* *4. Authority to produce medicines for export based on a Paragraph 6 request as a limited exception (TRIPS Art. 30— untested);* *5. Authority to produce medicines for export on humanitarian grounds as a limited exception (TRIPS Art. 30— untested);* *6. Authority for wholesalers and other buyers to export patented medicines already sold by patent holders to other developing countries to satisfy their parallel importation needs (TRIPS Art. 6);* *a. Consider making it an anti-competitive practice for a patent holder to restrict quantities or to place contract limits on right to "parallel export;"* *7. Require least costly methods of differentiation required to satisfy the Paragraph 6 Implementation Agreement's provisions concerning danger of product diversion.* *8. Encourage technology transfer to developing countries without capacity to manufacture medicines.*

Although it is beyond the scope of this paper to suggest actual language for amendment of domestic legislation, it is possible to outline some of the desirable features of such reform. However, when actually drafting implementing legislation, developing countries should be leery of technical assistance from traditional sources like WIPO and USAID. Despite refraining from comprehensively addressing all the permutations of legislative reform, this paper will directly address three areas of special concern: implementing the August 30 Agreement, energizing competition policy, and regulating voluntary licenses.

4.1 Implementing the August 30 Paragraph 6 Implementation Agreement

Actual implementation of the August 30 Paragraph 6 Implementation Agreement will require careful legal and regulatory implementation in both importing and exporting countries. Despite arthritic flexibilities in the Agreement, countries should craft legislation that tries to make the system as streamlined and efficient as possible. Rob Weissman of Essential Action has offered guidelines for exporting countries aimed at streamlining production for export:

> 1. Exporting country authorities should grant all applications for a compulsory license by a potential exporting manufacturer, contingent on a showing by the exporter that they plan to export in response to a request by an eligible importer.
> 2. A country is an eligible importer if it is a least-developed country, or any country that has made a notification to the Council for TRIPS of its intention to use the system as an importer, and which makes its own determination that it lacks sufficient manufacturing capacity to met its needs.
> 3. Licenses should authorize production of a quantity needed by the eligible importer. The license should be open-ended, so that exporters are authorized to export, over time, whatever amounts an importing country indicates it needs, subject to a system whereby the importing country provide notification of the required amounts, and those amounts are disclosed on a timely basis in a manner consistent with the WTO system for transparency.[155]

155. This open-ended license is a little risky given that the Paragraph 6 Implementation Agreement specifies that an export license must be for a specific quantity of a specific medicine. Weissman's proposal certainly makes sense in that it is onerous to require iterative license applications when transparency could be achieved merely by notifications concerning new quantities.

4. The term of the license should be for the life of the patent in the exporting country, unless the importing country indicates that it is no longer eligible.
5. There should be no requirement in the exporting country for a prior negotiation with the patent holder, and certainly not if one took place in the importing country. The TRIPS obligation for negotiation for a "reasonable period of time" shall be deemed met by negotiations, if required, that occurred in the importing country.[156]
6. The Paragraph 6 implementation decision obligates exporters to distinguish their products as produced under the implementation decision. The main concern is to ensure they are not confused with patented products, and thereby potentially subject to diversion to countries where the patent owner maintains a marketing monopoly. The most important distinguishing feature is to use a different trademark name for the export product. Exporting countries should require exporters either to use a different trademark name from the patented product, or only a generic name. Exporters should also be encouraged to use different external packaging from the patent holder, including marks indicating that the product is not for re-export. Where there is no medical reason to the contrary, and where the cost of doing so is de minimis, exporters should alter the color and/or shape of products to distinguish them from the patented version.
7. Before shipment, exporters should be required to post on their website (or, as an alternative at their discretion, the WTO website), the quantities being supplied and the distinguishing features they have applied to the product or packaging.
8. Compensation. The WTO requirements for compensation under a Paragraph 6 export compulsory license is the standard of "adequate remuneration" from Article 31(h) of the TRIPS. This is a less stringent standard than "reasonable commercial terms." Under the terms of the Paragraph 6 Agreement, the exporting country is required to set compensation, taking into

156. Weissman proposes that prior negotiations should generally not be required in the exporting country despite the language to the contrary in Article 31(b) of TRIPS. His argument is most cogent when prior negotiations have already occurred in the importing country where a patent bar exists. His argument also makes sense if the importer is a no-patent country, that country's access should not be delayed by negotiation rights that would not occur if the country had domestic manufacturing capacity. Despite the logic of Weissman's argument, some cautious exporting countries would provide for a period of prior negotiations given the specter of an Article 31(b) challenge.

> account the economic value of the product in the importing country. The importing country can waive compensation when compensation is paid in the exporting country. ...
> Wherever compensation is set, the key issue is to ensure the compensation system is simple, quick and predictable . . . [recommending royalties ranging from two to six percent be set by an appropriate administrative body].
> 9. The validity of a compulsory license in the exporting country shall be subject only to administrative review. Injunctive relief should not be available to the patent owner.
> 10. The implementing legislation should ideally apply to all healthcare inventions, and at least to all pharmaceutical products, defined in the Paragraph 6 Agreement as inclusive of all products of the pharmaceutical sector, including active ingredients needed for manufacture of pharmaceuticals and diagnostic kits. Implementing legislation should specify that it applies to vaccines.[157]

Weissman's proposals for legislative and regulatory reform in exporting countries would apply nearly equally to importing countries where a patent bar exists. Importing-country legal reform should: (1) permit compulsory licenses responding to any public health need, (2) apply to all healthcare products in the pharmaceutical sector, (3) allow administratively easy and minimally justified determinations of insufficient or inefficient local manufacturing capacity, (4) be open ended so that the licensee can provide whatever amounts the importing country needs, subject to proper notifications, (5) have a presumptive term of the life of the patent, though the term might be revocable based either on the termination of the public health need or meaningful expansion of economically efficient domestic manufacturing capacity, (6) require prior licensing negotiations on commercially reasonable terms, terms which may be regulated as discussed in subsection 4.3, *infra*, (7) preclude an import license royalty where compensation has been established in the exporting country and otherwise set presumptive royalties pursuant to streamlined administrative procedures, and (8) permit administrative review only and preclude injunctive relief to the patent holder.

Importing countries without patents on medicines, most likely least developed countries, will also be permitted to use the August 30 Paragraph 6 Implementation Agreement. Although they will not necessarily need to immediately adopt legislation permitting compulsory licenses, they should

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157. Robert Weissman, *Paragraph 6 Implementation Recommendations* (Feb. 3, 2004), *available at* http://lists.essential.org/pipermail/ip-health/2004-February/005892.html (last visited Mar. 7, 2004).

nonetheless enact legislation allowing for importation of medicines pursuant to the notification requirements of the August 30 Agreement.

4.2 Competition Policy Reform

One of the principle policy options that developing country have for accessing generic medicines is to invigorate their competition law as it applies to the pricing and licensing of pharmaceutical products. As the South African Competition Commission case demonstrates, aggressive, pro-access competition policy can be a formidable weapon in countries' efforts to obtain access to generics and to achieve economies-of-scale by inclusion of non-domestic markets. Because of the path-breaking nature of South Africa's emerging competition law, this subsection will analyze the application of that law in some depth so that other developing country members might consider the wisdom of adopting similar or improved measures.

Section 56 of the South African Patents Act 57 of 1978, as amended by the Intellectual Property Laws Amendment Act 38 of 1997, covers four specific circumstances whereby "(1) any interested person who can show that the rights in a patent are being abused may apply to the commissioner in the prescribed manner for a compulsory license under the patent."[158] The legal definitions of abuse of patent are quite specific:

1. *Non-working on a commercial scale or to an adequate extent (within a 3 or 4 year period of filing the patent application or certification of the patent) and there is no satisfactory reason for such non-working (sub-sec. (2)(a)).* The requirement of working to "an adequate extent" is somewhat imprecise, but does appear to cover supply amounts that are deficient in terms of market demand.
2. *Demand for the product is not being met to an adequate extent and on reasonable terms (sub-sec. (2)(c)).* The statute appears to require the demand to be an actual not merely anticipatory. In South Africa, there is no doubt that the true demand for AIDS medicines is not being met primarily as a result of high prices for medicines. Thus, the question becomes whether the

158. The State itself may apply for compulsory licenses under the Patents Act Section 4 which permits the Minister of State to seek a voluntary license for the use of the patented product for public purposes and in default of such voluntary agreement for the Minister to filed application to the Commissioner of Patents for an involuntary use (compulsory license) on terms or conditions to be set by the Commissioner. Section 78, permits the government to go even further and to "acquire" any invention or patent. Under the Constitution, the government could also "take" the patent and pay just compensation.

"reasonable terms" provision includes price. Fortunately, there appears to be little doubt that the phrase "reasonable terms" refers primarily to the price charged.[159] Even though drug companies have dramatically lowered prices, frequently by as much as eighty-five percent, current conditional discount prices by pharmaceutical patent holders are still three or four times as expensive as the much cheaper generics offered by Cipla, Rambaxy, and Hetero of India. Moreover, the price differentials are much sharper in the private sector where the drug companies continue to seek higher profits (private sector ARVs still cost over $2000/year in South Africa in 2003). Thus, because of unreasonable pricing in the private sector and comparatively unreasonable pricing terms even in the public and NGO sectors, a strong case could be made for the issuance of a compulsory license under this subsection.

3. *Refusal to grant a license on reasonable terms that prejudices an existing or emerging trade or industry and it is in the public interest to grant a license (sub-sec. (2)(d)).* This provision potentially applies to the issue of pharmaceutical access.[160] If the provision were to be interpreted to consider patents to be essential facilities, especially with respect to fixed-dose combinations, this provision would be much more helpful. In general it would be highly desirable for a patent scheme to include an explicit refusal to deal provision.[161]

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159. *James Lomax Cathro's Applications* (1934) 51 RPC 75, 82.

160. In the only reported case to date, the Supreme Court of Appeal denied an application for a compulsory license. Syntheta (Pty) Ltd v Janssen Pharmaceutica NV & Another, 1999(1) SA 85 SCA. The Appellant presented two allegations of abuse of patent: (1) the non-working of the patented invention in South Africa on a commercial scale, or to an adequate extent (section 56(2)(a)); and (2) the refusal of the patentee to grant a license on reasonable terms, being the Appellant's offer of six percent royalty on selling price (section 56(2)(d)). The Court found against the Appellant on both grounds because of an insufficiency of evidence. In relation to the subsection 2(d) ground, the court focused on the issue of public use and need. This focus represents a signal that 'public benefit' can be an important factor.

The computation of royalties also vexed the Court. It relied on the English decision of *Hoffmann-La Roche & Co AG's Patent (1973) RPC 601* in suggesting that computation of royalty should, at a minimum, take account of three elements, namely: (1) the patentee's expenditure on research and development; (2) the patentee's expenditure on promotion; and (3) a servicing of the capital element to allow a reasonable return on the preceding two elements.

161. There is European precedent for a refusal to license a key chemical intermediate for a drug effective against tuberculosis. ICI & Commercial Solvents Corp. v. Comm'n of the E.C., 223 E.C.R., 250 (1974) (abstracted in *Refusal by a Dominant Firm to Sell Raw Materials*, 19 Antitrust Bull. 605-18 (1974)). The United Kingdom has also permitted compulsory licensing

4. *Demand is being met by importation and the price is excessive in relation to the price charged in the countries where the patented article is manufactured (sub-sec. (2)(e)).* Since most pharmaceutical manufacturing is done in the United States and in rich European countries where prices are high, there is no "unfavorable price discrimination" in South Africa on most drug prices compared to First World prices. However, some patented medicines are more expensive in some developing countries than in the country of origin. In these limited circumstances, South Africa could issue a compulsory license.[162]

In addition to the Patent Act, the South African Competition Act 89 of 1998 provides remedies for anti-competitive practices and presumably permits the issuance of open compulsory licenses for anti-competitive pricing practices by the pharmaceutical industry. Section 8 of the South African Competition Act prohibits dominant firms from engaging in excessive pricing, refusing access to an essential facility, and engaging in other exclusionary acts:

8. Abuse of dominance prohibited. It is prohibited for a dominant firm[163] to -
(a) charge an excessive price to the detriment of consumers;
(b) refuse to give a competitor access to an essential facility when it is economically feasible to do so;
(c) engage in an exclusionary act, other than an act listed in paragraph (d),[164] if the anti-competitiveeffect

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when a patent owner has refused to grant a license on reasonable terms under section 48 of the Patents Act. In a recent ECJ opinion, the court held that "refusal to grant a license to use protected intellectual property constitutes an abuse [under Section 82 of E.U. competition law]" where the potential licensee has "the intention of producing goods and/or services with different characteristics." Ingrid Hering, *ECJ Opinion Could Lead to Uncertainty* (Oct. 13, 2003), *available at* http://lists.essential.org/pipermail/ip-health/2003-October/005420.html (last visited Feb. 12, 2004).

162. A more direct route with respect to differential pricing across countries, however, is parallel importation under the Medicines and Related Substances Control Act No.101 of 1965, as amended.

163. Section 7 states "A firm is dominant in a market if—(a) it has at least 45% of that market; (b) it has at least 35%, but less than 45%, of that market, unless it can show that it does not have market power; or (c) it has less than 35% of that market, but has market power.

164. (d) engage in any of the following exclusionary acts, unless the firm concerned can show technological, efficiency or other pro-competitive gains which outweigh the anti-competitive effect of its act—

(i) requiring or inducing a supplier or customer to not deal with a competitor;

(ii) refusing to supply scarce goods to a competitor when supplying those goods is

of that act outweighs its technological, efficiency or other pro-competitive gain; . . .

Section 1 provides key definitions:[165]

(viii) 'essential facility' means an infrastructure or resource that cannot reasonably be duplicated, and without access to which competitors cannot reasonably provide goods or services to their customers;
(ix) 'excessive price' means a price for a good or service which—
(aa) bears no reasonable relation to the economic value of that good or service; and
(bb) is higher than the value referred to in subparagraph (aa);
(x) 'exclusionary act' means an act that impedes or prevents a firm entering into, or expanding within, a market;
(xii) 'goods or services', when used with respect to particular goods or services, includes any other goods or services that are reasonably capable of being substituted for them, taking

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economically feasible;
(iii) selling goods or services on condition that the buyer purchases separate goods or services unrelated to the object of a contract, or forcing a buyer to accept a condition unrelated to the object of a contract;
(iv) selling goods or services below their marginal or average variable cost; or
(v) buying-up a scarce supply of intermediate goods or resources required by a competitor.

165. Section 1 also provides guidance on interpretation of the Act:
(2) This Act must be interpreted—
(a) in a manner that is consistent with the Constitution and gives effect to the purposes set out in section 2; and
(b) in compliance with the international law obligations of the Republic.
(3) Any person interpreting or applying this Act may consider appropriate foreign and international law.

Section 2 defines the purposes:
2. Purpose of Act
The purpose of this Act is to promote and maintain competition in the Republic in order
(a) to promote the efficiency, adaptability and development of the economy;
(b) to provide consumers with competitive prices and product choices;
(c) to promote employment and advance the social and economic welfare of South Africans;
(d) to expand opportunities for South African participation in world markets and recognise the role of foreign competition in the Republic;
(e) to ensure that small and medium-sized enterprises have an equitable opportunity to participate in the economy; and
(f) to promote a greater spread of ownership, in particular to increase the ownership stakes of historically disadvantaged persons.

> into account ordinary commercial practice and geographical, technical and temporal constraints; . . .

In its recently announced decision, the South African Competition Commission supported three theories for issuing a pharmaceutical compulsory license.[166] Under the first theory, compulsory licenses should be granted whenever it can be shown that there is a gap between need for the medicine and its accessibility due to excessive pricing, in other words, whenever an "above market value" or supra-competitive price contributes to the access gap. The second theory involves the failure to grant voluntary licenses, which can be considered exclusionary where the anti-competitive effect of non-licensing outweighs any "technological, efficiency or other pro-competitive gain." Under the third access-to-an-essential-facility theory, a compulsory license should be issued whenever a patent holder's failure to grant voluntary licenses denies consumer access to a competitor's product. This theory has particular salience with respect to downstream innovation, such as fixed-dose combination drugs where a generic company is seeking a license to make a pill combining medicines patented by several different companies.

In adopting pro-consumer competition policy challenging drug company prices and refusals to license, developing countries would be charting relatively new territory. Anti-trust/intellectual property regulations and jurisprudence in the United States and European Union have generally evolved to support the interests of intellectual property holder at the expense of consumers and of market competition when construing the essential facilities doctrine.[167] Opposing this trend, some commentators suggest that it is appropriate "to attempt, in some way, to balance the costs of monopoly pricing

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166. Although the Competition Commission did not directly adopt a price discrimination theory, a dominant firm may be found guilty of prohibited price discrimination if the firm discriminates between purchasers in the price charged. §§ 9(1)(b) & 9 (c)(ii). At present, pharmaceutical companies discriminate significantly between the public and private sectors in for antiretrovirals and other drugs. Although some differences might be accounted for because of bulk purchase, clearly these discounts are not related solely to cost. On the other hand, it is highly desirable that the public sector obtains deep price discounts and it would be an unconscionable outcome if companies reacted to the price discrimination issue by revoking public sector discounts. Since the long-term public health mandate is for cheap medicines in both the public and private sector, it seems desirable to seek compulsory licenses on the basis of price discrimination while carefully balancing the risk of a backlash from the pharmaceutical companies.

167. *See* Robert Pitofsky et al., *The Essential Facilities Doctrine Under U.S. Antitrust Law*, 70 ANTITRUST L.J. 443 (2002); Valentine Korah, *The Interface Between Intellectual Property And Antitrust: The European Experience*, 69 ANTITRUST L.J. 801 (2002); Sergio Baches Opi, *The Application of the Essential Facilities Doctrine to Intellectual Property Licensing in the European Union and the United States: Are Intellectual Property Rights Still Sacrosanct?*, 11 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 409 (2001).

associated with the specific practices against the incentives to innovation associated with the patent system."[168]

It is well beyond the scope of this article to fully articulate and defend a new competition law for developing countries. Despite this hesitance, however, it is appropriate to note that the pro-innovation effects of compulsory licenses in marginal developing country markets on drugs that have global sales is much less problematic than effects would be in dominant markets.[169] It is also appropriate to note that many developing countries have internal and domestic obligations to promote progressive realization of the right to health, and that obligation should inform the promulgation, implementation, and interpretation of their positive law, including their competition law. Finally, the real impact of widespread lack of access to higher priced proprietary medicines must be taken into account in balancing the tradeoffs involved in redressing a refusal to grant a patent license on reasonable terms and a refusal to discount medicines closer to their true costs of production.

As previously discussed, the remedial implications of a robust competition policy should also be considered. A competition-based compulsory license should ordinarily permit access to confidential drug registration data despite any data exclusivity rules to the contrary. Likewise, the license might also require access to manufacturing know-how. With these features in place, the risk of a competition-based compulsory license would generate even greater pressure for the issuance of voluntary licenses.

4.3 Regulating voluntary licenses

Voluntary licensing agreements result from negotiations between patent holders and other entities and are minimally regulated in the North.[170]

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168. John Barton, *Patents and Antitrust: A Rethinking in Light of Patent Breath and Sequential Innovation*, 65 ANTITRUST L.J. 449, 459 (1997).

169. "Research to date suggests that if compulsory licenses are taken in less significant markets, their impact on innovation should be marginal." Chien, *supra* note 145, at 893.

170. Michael A. Friedman et al., *Out-licensing: A Practical Approach for Improvement of Access to Medicines in Poor Countries*, 361 LANCET 341-44 (2003); M. Howard Morse, *Intellectual Property Licensing: The Intersection Between Intellectual Property Rights and the Antitrust Laws*, 1355 PLI/CORP 947 (2003). Although the United States generally regulates intellectual property licenses under a rule of reason standard, it has passed statutes and regulations both permitting and restricting certain licensing practices. *See* U.S. Dep't of Justice & Fed. Trade Comm'n, Antitrust Guidelines for the Licensing of Intellectual Property (1995). For example, exclusive licensing and territorial limits are expressly permitted under U.S. patent law, 35 U.S.C. § 261 (2000), as are unilateral refusals to license that do not illegally extend a patent right, § 271(d)(4). However, the United States has also passed guidelines questioning certain horizontal licensing practices including naked price fixing, output restraints, market division, minimum resale prices, and certain price maintenance agreements. IP Guidelines ¶ 3.4. In the European Union, licensing practices by patent holders are also regulated with a relatively light touch, but exceptional circumstances, including harm to particular competitors, may create an obligation to grant a license, particularly when the new license facilitates the sale of a "new" product. *See* Joined Cases c-241/91 & c-242/91, Radio Telefis Eireann v. Comm'n,

Ordinarily voluntary licensing agreements allow third parties to use a patent holder's patent to produce, market, or otherwise distribute the patented product normally in exchange for a royalty or licensing fee to the patent holder. In addition to requiring agreed-upon compensation for licensing, the patent holder commonly imposes restrictions on the sale or transfer of the license and on the geographical distribution and marketing of the affected product. In addition, the patent holder can limit the duration of agreement and can even make it terminable at will or revocable on certain conditions. When voluntary licenses are relatively unregulated, pharmaceutical companies can enforce terms on the amount of compensation, permitted usages, and distribution, especially export.

To counterbalance the risk of anti-competitive outcomes in voluntary licenses mandated by compulsory licensing schemes, developing countries could choose to regulate the following pro-competitive/commercially reasonable terms of voluntary licenses: (a) expansion of geographical scope and explicit options for export within a Paragraph 6 Implementation Agreement authorized regional trade group, (b) prohibition of sector limitations (no public sector or NGO-only sector clauses), (c) non-exclusivity, (d) direct permission to produce fixed-dose combination medicines, (d) requirements of some degree of technology transfer and/or manufacturing know-how, (e) access to confidential test data for purposes of establishing bio-equivalence, and (f) public disclosure of royalty rates negotiated within a range of reasonableness. This kind of regulation of voluntary licenses to prevent anti-competitive practices is directly authorized by Article 40 of the TRIPS Agreement.[171]

1. **Geographical restrictions**. For voluntary licenses to be of any real use in increasing access to high quality, affordable medicines, the licensee has to be able to achieve economies-of-scale sufficient to justify investment in human and physical capacity. For a few countries and for a few drugs, the internal market may be sufficiently large and/or rich to justify investment by the licensee and to achieve meaningful economies-of-scale. However, for many smaller economies and/or economies with severely limited purchasing power, efficient economies-of-scale can only be achieved by means of regional markets. As a general proposition, therefore, voluntary licenses should not be unduly burdened with unrealistic geographical restrictions. In this context, permitting licenses for distribution throughout Africa would certainly make some sense, both to countries with and without patents in place. Likewise, an

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1995 E.C.R I-743.

171. This right is subject to a process of consultation between affected Members with respect to anti-competitive licensing agreements.

even broader distribution to all "developing" countries might also make sense.[172]

Another reason to have few geographical restrictions with respect to voluntary licenses is the issue of non-exclusivity. Ordinarily, it will not be desirable to give a voluntary license to one producer only. Of course, there is a complex balancing act to figure out how many licenses can exist within a given national or regional market before the number of licenses begins to create disincentives to entrepreneurial investment in capacity. On the other hand, recent research indicates that prices go down dramatically, in the absence of price controls, only when a certain number of generic competitors enter the market. Rather than reproduce a small number of generic monopolists, each with its own individual market concentration, it would be better, as a matter of policy, to open up the geographical scope of a license to permit competition between licensees, each of whom could achieve economies-of-scale but still be subject to stiff competition in any given market. An alternative route to affordability would be voluntary price control terms in the license itself. However, these price-ceiling agreements might raise some competition concerns in some countries though price maintenance/fixing concerns are usually a problem with respect to price floor, not price ceilings.

Despite urging few geographical restrictions with respect to developing country markets, it might be appropriate to permit patent holders to impose geographical restrictions with respect to developed country markets. In this regard, and into the foreseeable future, the industry is going to be able to affect national legislation in developed economies to prohibit parallel importation from developing countries where the industry has offered discount prices or where it has issued voluntary licenses. However, with a geographical limitation, there will be a contractually enforceable patent bar in developed countries as well. In this regard, the industry might well be concerned about allowing contractual sanctions for improper diversion of licensed drugs to developed economies. However, as long as national exhaustion (United States) and regional exhaustion (European Union) are the only options within developed countries, the prospects of product diversion and gray markets is greatly reduced. Even so, a given company could impose some reasonable sanction on intentional breaches of geographical limitations by a license holder. These sanctions could range all the way from multiple royalties to eventual termination of the license for repeated bad faith breaches.

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172. Some might wonder if a country has sovereign authority to require a patent-holder to relinquish patent rights in another country in order to prevent the issuance of a compulsory license in the subject state. Although countries might not be able regulate truly voluntary licenses in this way, the voluntary licenses in this instance are part of a compulsory licensing scheme wherein a nation has a sovereign interest in increasing access to medicines to address a valid public health concern. In these special regulatory circumstances, it seems appropriate to regulate geographical restrictions so that generic producers can reach efficient economies-of-scale and thus sell medicines even more cheaply.

2. **Market segmentation**. Market segmentation, e.g., public vs. private, is problematic especially in developing countries. At present, major pharmaceutical companies have made a decision to seek profits off the small elite populations within developing markets, even at the cost of unaffordability for the vast majority of people infected with diseases such as AIDS. However, a generic licensee is going to want some access to private sector buyers with money to spend, rather than bet solely on uncertain public expenditures by poor countries or evaporating donor support for the Global Fund. It may be galling to proprietary companies that even small but rich "profit centers" will be lost, but if they really want to contribute to the global treatment, they will have to bite the bullet and give up on public/private sector differentiation.

One problem with trying to maintain a private sector/public sector market differentiation is that it will become virtually impossible to secure distribution channels so as to prevent theft, corruption, and diversion to the more lucrative private market, undercutting the marketing advantage there anyway. Similarly, even in the private sector, most Africa developing country consumers cannot afford moderately discounted ARVs. Thus, if there are large price differentials between medicines in the private and public sector, an additional effect of high prices in the private sector might be disruptive migration of more affluent HIV-positive consumers to the already overburdened public sector. Accordingly, if developing countries want to get the maximum treatment to the most people at the lowest cost and if they want to avoid disruption of the public sector by migration from the private sector, drug companies will have to give up their goal of market segmentation.

Despite arguing for basic price parity between the public and private sector, it might be possible to have some slight differences in royalty payments due based on defensible market segments, e.g., 5% vs. 10% royalties. The problem would be to avoid pricing differentials that would prompt the disruptions described above.

3. **Non-exclusivity**. The general principle for compulsory licenses should be non-exclusivity, meaning that multiple licenses should be issued. To the extent that regulation of voluntary licenses is motivated by a desire to enhance competition, regulators would want to disrupt the more normal practice of simply transferring or even sharing the monopoly. Therefore, there are arguments that the best practice might be the issuance of open licenses. However, too many entrants can also deter investment and entry by a particular licensee. Canada is the country that has had the greatest experience in issuing compulsory licenses for pharmaceutical products and it granted an average of three licenses per drug, with a variance of one to eleven.[173] The WHO, in its procurement practices tries to ensure the presence of at least five competitors. Prices approach the marginal cost of production when there are

173. F.M. Scherer, *The Economics of Drug Patent Licensing*, WORLD BANK, June 24-25, May 2003, at 9.

8-10 competitors in a market.[174] Especially if licenses have no geographical limits and no market restrictions, more competitors can be licensed.

4. **Cross-licensing for fixed-dose combinations**. Clearly the licenses should permit freedom to research and cross-license fixed-dose combination medicines and other therapeutic advances. One of the greatest irrationalities in the current patent regime is that it creates disincentives for patent holders to develop rational drug combination therapies with their competitors. In the long run, this will become one of the main rationales for the issuance of compulsory licenses. Therefore, in the interest of promoting public health and of maximizing treatment compliance, the license should certainly permit, indeed promote, cross-licensing and combination of products.

5. **Manufacturing know-how and technology transfer**. To make voluntary licenses work and to avoid risks of poor quality drugs, the companies should be required to transfer technology. AIDS medicines in particular are complicated medicines needing special care in quality control to ensure bio-availability in a narrow range. Accordingly, licensees should not have to reinvent the wheel; they should get the very best assistance possible for transfer of technology and expertise. In this regard, voluntary licensors should specifically be required to transfer manufacturing know-how as well as essential technologies. In the event of trade secrets, the drug company can require confidentiality.

6. **Registration data**. The voluntary license should include access to and/or comparison against otherwise confidential data submitted to a drug registration authority to secure market approval. The voluntary licensee should not have to conduct independent clinical studies, but instead should be expressly permitted to establish bio-equivalence via cross-over studies. In the special case of fixed-dose combinations, where a combined product registration dossier has not previously been filed, patent holders should have even greater obligations to permit access to underlying data so that fixed-dose combination registration can be eased.

7. **Duration**. The time line on voluntary licenses should be long, with a presumption of renewability except for cause, so that generic manufacturers can estimate their market and invest in productive capacity. Many newer medicines are hard to produce. High quality pharmaceutical capacity is expensive and time-consuming to build. Registration in multiple countries is also expensive. Thus, the time horizon must be long enough to secure investment under conditions of uncertainty.

8. **Royalty rates**. The regulation of voluntary licenses should include some attempt to limit royalty rates. Relatively small royalties in the range of two to ten percent have become traditional in the pharmaceutical field. Setting rates in this general range could be done by means of legislative findings about a

174. David Reiffn & Michael Ward, Generic Drug Industry Dynamics, working paper, *at* http://www.uta.edu/faculty/mikeward/GenericDynamics.pdf (last visited Mar. 8, 2003).

presumptive permissible range. This range could be further calibrated by reference to the list of factors that might sensibly affect royalties including public expenditures, inventiveness, research and development costs, remaining life of the patent, and purpose of use.

5. POSSIBLE RAMIFICATIONS OF GLOBAL FUND AND UNITED STATES PROCUREMENT RULES

Because of fiscal constraints, many developing countries will rely on donor funding for purchasing important on-patent medicines, including antiretrovirals and combination anti-malaria medicines containing Artemisinin. These funding sources will in turn often prescribe procurement policies for grant recipients. Some of these requirements may impact sourcing decisions, including the decision whether to import medicines from abroad or to produce them domestically. Generally these procurement policies address questions of price, quality, and intellectual property legality.

5.1 Global Fund policies

C. PROCUREMENT AND PRICING

7. Procurement practices

The Fund will require that, as a minimum, Recipient procurement offices and any contracted agencies/services adhere to the Interagency Operational Principles for Good Pharmaceutical Procurement.[175] Where practices differ from the Interagency Guidelines, Recipients or their agents must demonstrate to the LFA comparable systems for competitive bidding within a group of pre-qualified suppliers, transparency and accountability to their practices, and their application of necessary quality assurance mechanisms. Recipients should also demonstrate the existence of a full set of contractual documentation to govern each transaction.

8. Procurement responsibilities

a) The Recipient is responsible for all procurement, with the use of contracted local, regional or international procurement agents being at the discretion of the Recipient. The exception to this would be for those product categories for which local procurement capacity is insufficient, as judged by the Procurement and Supply Management Assessment. For such product categories, Recipients would be required to use established regional or international procurement services and will be informed by the Fund on which mechanisms are available.

b) Even for product categories for which Recipients have procurement capacity, the use of capable regional and global procurement services is encouraged wherever pooling of demand lowers prices for products of assured quality.

175. World Health Organization, *Operational Principles for Good Pharmaceutical Procurement* (Interagency document). WHO/EDM/PAR/99.5, *available at* http://www.who.int/medicines/library/par/who-edm-par-99-5/who-edm-par-99-5.pdf (last visited Mar. 7, 2004).

9. Monitoring supplier performance

Recipients are responsible for monitoring the performance of suppliers with respect to product and service quality and for submitting that information electronically for web publication through a mechanism established by or identified by the Fund. Reporting guidelines for supplier performance should be specified by the LFA, according to guidelines provided by the Secretariat of the Fund.

10. Lowest possible price

a) The Fund requests Recipients to use Good Procurement Practices, which includes competitive purchasing from qualified manufacturers and suppliers, as outlined in section B of these recommendations, to attain the lowest price of products. The Fund encourages Recipients to comply with national laws and applicable international obligations in the field of intellectual property including the flexibilities provided in the TRIPS agreement and referred to in the Doha declaration in a manner that achieves the lowest possible price for products of assured quality.

b) The Fund encourages the voluntary efforts of pharmaceutical companies to expand current tiered or preferential pricing arrangements, among other mechanisms, to promote differential pricing.

c) Disclosure of information on prices paid for purchases by Fund Recipients is a matter of principle and will facilitate a process leading to lower prices. The Fund will ensure that information on prices paid on products of assured quality with the same conditions (e.g., including other goods or services included in the contract) is made publicly available. The disclosure of this information will be pursued by the Fund. A methodology for assuring this transparency will be presented to the Board by January 2003.

d) In the cases of this policy, price refers to DDU costs—delivered duty unpaid. The approach taken may be to publicly list average, minimum, maximum, and mode prices and/or prices for individual companies and/or Recipients. This choice requires further consideration by the Fund to identify or develop standard methods to ensure to the extent possible that price information is based on a consistent set of definitions. It is understood that price comparisons are indicative and must include special "add ons"/conditions included in the price and that actual prices will vary.

E. BUDGETING AND FINANCE

17. Direct payment to suppliers upon delivery

Prompt payment in compliance with the terms of payment of the contractual provisions encourages timely delivery of products and reduces transaction costs. Direct payment to suppliers by the Trustee, on confirmation of delivery, will be allowable upon request of the Secretariat if, as confirmed by the LFA, such payment arrangements are expected to reduce costs and to be consistent with necessary accounting requirements.

18. Exemption from duties, tariffs and taxes

a) The Fund strongly encourages the relevant national authorities in the Primary Recipient's country to exempt from duties and taxes all public health products financed by the Fund to NGOs, groups of NGOs, or national authorities, or any other PRs.

b) In any case, Fund resources may not be used to pay duties, tariffs, local or national taxes on public health products procured with Fund resources. If payment of such fees is required by relevant national authorities, such payment is the responsibility of the Recipient.

19. Additionality of Fund resources and contribution to sustainability

a) The Fund encourages Recipients to manage and to apply Fund resources as part of a sustainable long-term plan for local public health financing. Recipients will be required to declare in the original proposal to the Fund other international financing and product donation programs being utilized by Recipients. Ongoing indicators must show the magnitude of product financing supported by domestic versus international financing.

b) Programs which include consumer cost recovery mechanisms are eligible for funding by the Fund when such programs are part of a pre-existing healthcare financing policy, which should be specified in the proposal to the Fund; in these cases, the budget request to the Fund must not duplicate costs to be reimbursed by consumers.

21. Prices used for budgeting proposals

a) For budget requests for pharmaceutical products, proposals to the Fund must use the lessor of current procurement prices, firm offers from suppliers, or existing public price information sources specified by the Secretariat in the Guidelines for Proposals. A rationale for budgeting using prices other than those specified above should be described in the proposal. All prices should be expressed in standard trade terminology to allow transparent comparison.

b) During implementation, these budgeted prices will not act as a defined reimbursable ceiling or floor to the full cost of products paid by the Recipient, provided that products are of assured quality and that procurement practices adhere to the policies of the Recipient and Fund.

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The Global Fund has adopted a lowest cost pricing requirement.[176] In general, this means that grant recipients will be obligated to procure the lowest cost medicine that meets other standards concerning quality and legality.[177] The Board of the Global Fund considered the possibility of permitting a premium for domestically produced products.[178] This preference would have been consistent with the then existing policy of the World Bank, which provided for a ten to fifteen percent domestic preference margin to local manufacturers on government tenders.[179] However, the Board rejected adopting a domestic preference mark-up even where the government was the

176. *See generally* Health Action International, *Assured quality and lowest price: What the Global Fund requires for buying medicines*, *at* http://www.haiafrica.org/globalfund/GF%20HAI%20Factsheet.pdf (last visited Mar. 7, 2004).

177. *See generally* Report of the Third Board Meeting, Oct. 10-11, 2002, GF/B4/2, *available at http://www.globalhealth.org/view_top.php3?id=138 (last visited Mar. 7, 2004)*; Report of the Fourth Board Meeting, January 29-31, 2003, GF/B5/2; Guidelines for Proposals, The Global Fund, March 2003, *available at* http://www.theglobalfund.org/en/apply/proposals/ (last visited Mar. 4, 2004); Report of the Portfolio Management and Procurement Committee to the 5th Board Meeting, GF/B5/9, *available at* http://www.haiafrica.org/globalfund/refs.htm (last visited Mar. 4, 2004) [hereinafter Report of the Fourth Board Meeting]. Of course, the basic procurement price is only part of the total cost of procuring and delivering the medicine to end-users. Other elements can add significantly to actual costs: freight/shipping, insurance, registration, quality assurance, storage, internal transportation, dispensing, administration, distribution costs charged by intermediaries, duties, tariffs, and national and local taxes.

178. Report of the Fourth Board meeting, *supra* note 177. Although the PMC recommended up to a fifteen percent price premium, this recommendation was no adopted, meaning that recipients must continue to source at lowest cost.

179. World Bank Group, *Bidding for Goods and Works Contracts*, *available at* http://www.worldbank.org.ru/eng/constant/answer4.html (last visited Feb. 7, 2004).

purchasing entity.[180] Accordingly, whenever patented antiretrovirals or other drugs can be lawfully sourced more cheaply from international producers, the recipient will be required to utilize that source of supply. As an example of the stringency of this requirement, the Global Fund requires that "all procurement of medications for Multi-Drug Resistant TB (tuberculosis) must be conducted through the Green Light Committee."[181]

180. *See* Report of the Fourth Board Meeting, *supra* note 177.

181. *See* WHO, *Green DOTS plus & Green Light Committee*, WHO/CDS/TB/2000.283, *available at* http://www.who.int/gtb/policyrd/PDF/DOTSGLC.pdf (last visited Mar. 8, 2004). The Green Light Committee also serves an important function as the means by which the correct treatment of MDR-TB is assured as much as is possible through the dissemination of information and the review of existing TB treatment programs. The treatment of MDR-TB can be extremely complex. One of the concerns is that without a strong, existing DOTS program to oversee administration of the DOTS-Plus protocols, there is a risk of creating even stronger strains of MDR-TB, resistant to even the second and third line treatments.

B. QUALITY ASSURANCE

4. Compliance with quality standards

a) For any medicinal product to be eligible for purchase with Fund resources, its compliance with quality standards must be assured. For multi-source, off-patent products with available dosage from public pharmacopoeial quality standards, verification of product compliance with standards would be conducted in accordance with the existing national procedures of the Recipient's country.

b) Provided products are accepted by the national drug regulatory agency (NDRA) of the Recipient country (see 5 below), to be eligible for purchase with Fund resources any single or limited source product (that is, a medicinal product for which there are not publicly available quality assurance standards, analytic methods, and reference standards) must (a) have been found to be acceptable by the WHO-initiated UN Pilot Procurement Quality and Sourcing Project, or (b) have been authorized for consumption in its country by a stringent regulatory authority, or (c) have been authorized by the national drug regulatory authority in the Recipient's country. Option (c) is applicable only until December 31, 2004, after which suppliers must comply with one of the two standards as set out in (a) and (b)—and in all cases are subject to monitoring product quality standards prescribed by the Fund as in 6.1.

5. National drug registration

a) Products procured with Fund resources are subject to authorization by the National Drug Regulatory Authority (NDRA) in the country in which they will be used, following its standard practices for drug registration for pharmaceutical products. For products that have passed the UN Pilot Procurement Quality and Sourcing Project review, as described in above, NDRAs are encouraged to expedite registration by accepting WHO pre-qualification inspection and supporting dossiers in lieu of national requirements.

b) For products which have been authorized by stringent drug regulatory authorities, NDRAs are encouraged to expedite registration by accepting in lieu of national requirements the Executive Summary of the Common Technical Document (CTD) or Summary parts for quality, safety and efficacy together with all necessary information to perform quality control testing of products and necessary reference standards.

6. Monitoring product quality

a) Recipients, their procurement agents, or NDRA's must systematically draw random samples of pharmaceutical products purchased with Fund resources for quality control testing to monitor compliance with quality standards. Testing may be budgeted in proposals, to be funded by the Fund. For multi-source off-patent products with available public standards, samples should be sent to WHO-recognized laboratories in cases where the NDRA have no capacity for this testing.

b) For single- or limited-source products without public standards and pre-qualified by UN Pilot Procurement Quality and Sourcing Project, samples should be sent to WHO-recognized laboratories already participating in the WHO pre-qualification project in case the NDRA has no capacity. For single- or limited-source products that have been pre-qualified on the basis of authorization by a regulatory authority in an ICH and/or PIC/S member, testing shall be done by a laboratory identified by the purchaser as stated in the purchase contract. The laboratory should be a WHO-recognized laboratory, or a laboratory in ICH and/or PIC/S countries in case the country does not have identified laboratory capacity.

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National Drug Regulatory Authorities (NDRA) laboratories or laboratories recognized by the NDRA should be used for quality monitoring by the PR (principal recipient). To ensure the respective laboratories have adequate capacity for full pharmacopoeial testing, they must meet one of the following criteria: acceptance for collaboration with WHO pre-qualification project; accredited in accordance with ISO17025 and/or EN45002; accepted by a stringent authority.

Because poor quality medicines can have serious health and financial consequence, the Global Fund has adopted exacting quality standards during both the production and distribution process. If medicines do not contain the specified active ingredients in correct quantities, if quality and efficacy deteriorate because of improper handling or expiration, or if medicines contain harmful substances, patients will be exposed to substandard or even dangerous therapies that can lead to treatment failure, drug resistance, and even death. Accordingly, the Global Fund requires that pharmaceutical products procured with Fund resources be authorized by the relevant national drug regulatory authority (NDRA) in the country in which they will be used and that agency is instructed to follow its standard practices for drug registration of pharmaceutical products.

However, the Global Fund is not content to rely on potentially unreliable national safety certifications; thus it will require a separate quality assurance guarantee starting in 2005. At that time, pharmaceuticals will have to be pre-approved by the U.N. Pilot Procurement Quality and Sourcing Project[183] [WHO pre-qualification project] or be accepted for use in a country with a stringent NDRA. This is a far-reaching requirement that will dramatically affect countries' decisions to support local production. Unless they can buy AIDS, TB, and malaria medicines on their own, they will be required to have their domestic supplier go through the WHO pre-qualification process, a

182. *See* Chiang Mai, The Portfolio Management and Procurement Committee recommendation at the Sixth Board Meeting, GF/B6/9 (Oct. 15-17 2003).

183. WHO pre-qualification will not replace the requirement of in-country registration, but it should help fill a capacity gap in low-income countries that have difficulty independently assessing quality of medicines and manufacturers' adherence to Good Manufacturing Practice. The frequently updated list of pre-qualified medicines is not binding on governments, but it does provide evidence-based quality assessments of manufacturers and of key medicines. *See* WHO, http://www.who.int/medicines/organization/gsm/activities/pilotproc/pilotprocmain.shtml (last visited Mar. 8, 2004).

rigorous process that has already proved onerous and time-consuming for some experienced Indian producers. This process is particularly fraught with respect to fixed-dose combination ARVs where there is no pre-existing registration portfolio.

On the other hand, the Global Fund is also interested in speeding up the in-country registration of medicines that have been pre-qualified by the WHO or by a stringent registration authority. As an aid to fast-track approval of essential medicines, the Fund urges expedited approval for products that have been accepted by the WHO pre-qualification project or authorized by a stringent NDRA, one that is a member of the Pharmaceutical Inspection Convention/Scheme and/or the International Conference of Harmonisation.[184]

Since quality can deteriorate during distribution, the Global Fund also requires rigorous quality control testing thorough various stages of the supply chain from manufacture to final consumption. This testing too will need to be performed by a high-quality lab.

The WHO has just released a study documenting the growing problem of substandard and counterfeit medicines estimating that up to twenty-five percent of medicines consumed in poor countries are deficient and that the deficiencies are particularly problematic for high-markup products treating HIV/AIDS, tuberculosis, and malaria.[185] "Trade in substandard and counterfeit medicines is most prevalent in countries with weak drug regulation control and enforcement, scarcity and/or erratic supply of basic medicines, unregulated markets and unaffordable prices," according to the WHO press release. The risk of counterfeit medicines also rise "[w]hen prices of medicines are high and price differentials between identical products exist," inducing some consumers to seek medicines outside of the normal supply system. This finding highlights one of the dangers of market segmentation whereby drug companies seek to maintain higher profit margins in private sector sales at the same time that discount prices are available in the public or NGO sector. To redress these recurrent problems, the WHO recommends legislative reform to strengthen enforcement powers in drug regulatory authorities, strategies to reduce corruption and criminal activity, and international cooperation like its own pre-qualification program for HIV, AIDS, tuberculosis, and malaria medicines.

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184. The ICH brings together the regulatory authorities from the United States, the European Union, and Japan. *See* ICH, http://www.ich.org (last visited Mar. 8, 2004). The IPC/S is comprised of Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Liechtenstein, Malaysia, Netherlands, Norway, Portugal, Romania, Singapore, Slovak Republic, Spain, Sweden, Switzerland, and the United Kingdom. *See* IPC/S, http://www.picscheme.org/overview/picsauth.htm (last visited Mar. 8, 2004).

185. WHO, *Substandard and Counterfeit Medicines*, Fact Sheet no. 275 (Nov. 2003), *available at* http://www.who.int/mediacentre/factsheets/2003/fs275/en/print.html (last visited Mar. 8, 2004).

The net impact of the Global Fund's concerns about quality, bolstered by the recent WHO report, is that developing countries will need to be quite strict about quality issues for both imported and domestically produced drugs. Absent the Global Fund rule, there has been some concern that developing countries with weak NDRAs might be tempted to cut corners to register substandard domestically produced medicines. Obviously, this would be disastrous for the long-term control of infectious diseases and for treatment of chronic conditions; moreover, it would waste scarce fiscal resources. In sum, developing countries should be concerned about the quality of medicines not only price or country of origin. The required Global Fund standard is the lowest price for drugs of assured quality—both sides of the equation are important.

Global Fund—IP issues

"[I]n making its funding decisions, the Fund will support proposals which . . . [a]re consistent with international law and agreements, respect intellectual property rights, such as TRIPS, and encourage efforts to make quality drugs and products available at the lowest possible prices for those in need." (Framework Document, GFATM/B1/doc 4.)

"The Fund encourages recipients to comply with national laws and applicable international obligations in the field of intellectual property, including the flexibilities provided in the TRIPS . . . agreement and referred to in the Doha declaration, in a manner that achieves the lowest possible price for products of assured quality." (GF/B4/2)

The Global Fund "encourages" countries to procure products that are legal under national and international law, but it has not undertaken a close review of recipients' decisions in this regard. The Global Fund takes special pains to emphasize the use of flexibilities within the TRIPS Agreement and the Doha Declaration. (Given the adoption of the Paragraph 6 Implementation Agreement, its flexibilities should also now be considered.) At a minimum these flexibilities including sourcing from no-patent countries, parallel importation, non-predominate export pursuant to a "normal" compulsory license, and export pursuant to a "special" paragraph 6 compulsory license. However, there is also room for countries to source from countries using an Article 30 limited exception to patent rights. This option was not explicitly endorsed at the WTO, but it was not specifically rebuffed either.

A second and important feature of the Global Fund IP rule is that recipients are encouraged to use flexibilities "in a manner that achieves the lowest possible price." This requirement is designed to prevent "gaming" by developing countries with respect to their sourcing choices. For example, some countries might be tempted to issue compulsory licenses for local

production even where that production will be uneconomical with respect to the global market, where the lowest price for fixed-dose combination ARVs is now below $140/year. Although a country would certainly be able to preferentially source local products drawing from its own fiscal reserves, in using Global Fund money it is obligated to import cheaper medicines from abroad whether generic or proprietary. As a practical matter, this "lowest-cost" requirement, in conjunction with the intellectual-property-legality standard, requires developing countries to issue compulsory licenses open to both local production *and* importation so that they might eventually choose the most cost effective alternative.

At present, it is unclear whether Global Fund rules can be bent to permit developing countries to pay a domestic-production premium out of their own funds (lowest cost price reimbursed by the Global Fund, domestic premium paid by the recipient).[186] In the long run, however, this choice is terribly inefficient as it wastes scarce resources on commodity purchases that could more wisely be spent on health care infrastructure and systems and enhanced salaries for health care workers.

Since the announcement of the Global Fund's drug procurement policy, the World Bank has revised its guidelines for purchasing HIV/AIDS related medicines to match Global Fund rules in all material respects.[187] It too allows no preference for locally produced products and requires procurement of lowest cost products.[188] Likewise, it mandates WHO pre-qualification, as well as registration by the local drug regulatory authority,[189] and encourages fast track registration of WHO pre-qualified medicines.[190] Finally, the World Bank advances an interpretation of Article 39.3 of the TRIPS Agreement that permits a drug regulatory authority to establish bio-equivalence and to grant marketing approval by comparing generic data against proprietary data previously filed by the product innovator.[191]

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186. This option, even if it exists, would be subject to the Global Fund's principle of additionality, which requires countries to maintain or expand current fiscal commitments to the health sector. Thus, countries would at the very least have to appropriate additional funds to pay the price differential.

187. The World Bank, *HIV/AIDS Medicines and Related Supplies: Contemporary Context and Procurement—Technical Guide, available at* http://www1.worldbank.org/hiv_aids/docs/Technical%20Guide%20for%20HIV%20AIDS%20Final%20February%202004.pdf (last visited Feb. 25, 2004).

188. *Id.* ¶ 5.33.

189. *Id.* ¶ 4.76.

190. *Id.* ¶ 5.20. The World Bank also expressly endorses use of fixed-dose combination medicines, including fixed-dose combination generic ARVs. *Id.* ¶¶ 4.29 & 4.32.

191. *Id.* ¶ 2.14 and Appendix B, ¶ 63.

3.2 United States' PEPFAR policies

The United States was originally less than forthcoming about its planned procurement policies for the President's Emergency Plan for AIDS Relief [PEPFAR]. Given the historic alignment of U.S. policy and that of the pharmaceutical industry, however, it seemed likely that U.S. purchasing decisions would be slanted toward purchases of price-discounted, patented medicines. Evidence for this preference came from direct statements by certain administration officials who downplay the likelihood of generic purchases and instead tout the benefits of buying "American" and buying drugs of "highest" quality.[192] Moreover, there was mounting evidence that the United States intended to sidestep the WHO Pre-Qualification Project and that it would devise its own unilateral system for assessing safety, efficacy, and quality of generic drugs.

The clearest evidence of the U.S.'s eventually policy on drug procurement and its intent to discount the WHO Pre-qualification Project was contained in the CDC's call for proposals on PEPFAR (Funding Opportunity 04080)[193] which provides for $115 million in funding each of the next 5 years as part of the overall Bush Administration treatment proposal. The CDC has published "responses to inquiries" several of which address the issue of generic medicines.[194] Most on point is number 40:

> 40. **Question:** (a) When the U.S. Government endorses the use of safe and effective therapy, how is safety and efficacy confirmed? (b) For example, if the WHO says that something is safe and effective, would that be adequate?

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192. Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Disease, is reported as saying that there will not likely be any "direct purchase" of generic drugs. "It's likely we will try to get the best possible price from drug companies . . . for 'classic drugs,' where the efficacy is proven and the quality we are sure of." He nonetheless acknowledged that there might still be an opening for indirect purchases by local programs that buy generics directly through lawful sources. Sabin Russell, *AIDS Relief Showcase of Bush's Africa Tour: Critics Wary of Funding Level, Focus On Abstinence*, SAN FRANCISCO CHRON., July 7, 2003, at 2. Attacking the quality of generics has been a long-term strategy of PhRMA, which has used the twin-icons of piracy and substandard-quality to demonize the generic industry. *Id.* Even more recently, Randall Tobias, Mark Dybul, and John Lange, the PEPFAR leadership team, has repeatedly questioned whether WHO pre-qualified fixed-dose combination ARVs meet exacting quality standards. Although their challenge to fixed-dose combinations has varied over time ("there is no process, no principles, no standards in place today," "WHO is not a regulatory agency," "combinations have not been studied over a long period of time," and "we need to see the underlying data"), their most widely quoted statements question the fundamental safety, efficacy, and quality of the medicines and the specter of "endangering people's lives" and "provoking resistance."

193. *See* CDC, http://www.cdc.gov.od/pgo/funding/04080.htm (last visited Jan. 7, 2004).

194. *See* CDC, http://www.cdc.gov.od/pgo/funding/04080QA.htm (last visited Jan. 7, 2004).

> **Response**: (a) As stated in a previous response to your questions, the U.S. Government endorses the use of safe and effective therapy and diagnostics at the lowest possible cost. For the purposes of this program announcement, the following represents current guidance in this area:
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> For grantees to procure pharmaceuticals that are not *approved by* the U.S. FDA or another stringent regulatory agency, they would need to submit a waiver that would address the following four points: (1) the request must attest to issues of safety, quality and efficacy by demonstrating that the necessary information is available if requested (to be reviewed by appropriate authorities); (2) demonstrate the procurement is essential to the activity; (3) demonstrate savings; and (4) must be in accordance with national and international laws.
>
> For this announcement, other stringent regulatory agencies include drug regulatory agencies of Canada, Japan, and Western Europe. Grantees who plan to procure pharmaceuticals that are not *approved by the* US FDA or drug regulatory agencies of Canada, Japan, or Western Europe should submit a waiver that addresses the four points in the preceding paragraph.
> (b) No, a statement by the WHO that a pharmaceutical is safe and effective is not adequate.

It is important to note that at this time none of the generic antiretrovirals currently pre-qualified by WHO are registered by the FDA or any other stringent drug regulatory agency. The explanation for this is quite simple—it is unlawful in the United States or in the European Union to obtain final marketing approval for a generic product during the life of a patented medicine. Thus, U.S. procurement policies placed generic companies in a double bind—they were not permitted to seek final registration during the period of patent protection but they were condemned on quality grounds for not having obtained such regulatory approval. Caught in this Catch-22, generics will now be subjected to a recently announced stringent but expedited regulatory review by the FDA, a review that is likely to be equivalent to that required by a U.S. generic registrant proving bio-equivalence for the marketing of an off-patent medicine.

The newly announced FDA policy promises to expedite tentative approval of co-packaged and fixed-does combination HIV/AIDS medicines thereby granting a quality assurance that would permit purchases of AIDS medicines with PEPFAR funds. Although manufactures will have to re-establish bio-equivalence and Good Manufacturing Practices according to

criteria that are virtually identical to those already used by the WHO Prequalification Project in order to prequalify the very same medicines, the U.S. has agreed to expedite the FDA approval process to as little as two to six weeks for co-packaged drugs and to a somewhat longer, but still expedited, framework for fixed-does combinations. As an additional incentive to seeking tentative approval, the U.S. has also agreed to waive its usual $500,000 filing fee.

However, the U.S. has also made clear that it will continue to respect data exclusivity rights that might preclude even tentative approval of the newest AIDS medicines. Thus, medicines like tenofovir, atanazivir, and emtricitabine, all of which still enjoy data exclusivity as new chemical entities, will be immune from provisional registration at least during the first four years of their five-year data exclusivity. Even more problematic, when proprietary drug companies themselves eventually produce co-licensed fixed-does combinations, those new combinations may be considered new chemical entities or at least new products and thus be entitled to three to five years of exclusivity. This means, for example, that generic producers will not be able to produce WHO-recommended fixed-does combinations involving efavirenz for three to five years should Gilead, Merck, and Bristol-Myers Squibb succeed in registering their fixed-does combination first.

Despite the U.S.'s regulatory concessions and promises of speed, NGOs and activists are concerned that the U.S. has interposed an unnecessary, duplicative, and potentially burdensome process that requires generic companies to jump over additional hurdles to establish the quality of medicines that have already been vetted by the internationally recognized WHO Pre-qualification Project. And, it is hard to imagine that the expedited process will be truly fast given the volume of documentation required and the slow pace of scientific review and of inspecting manufacturing facilities overseas. Moreover, any delay in procuring generic drugs of assured quality is potentially problematic because PEPFAR grantees will be locked into supply chains, contracts, and procurement systems with higher-priced, proprietary manufacturers. Changing back from the U.S.-backed brand-name prescriptions will create chaos in the future as developing countries wean patients from one complicated drug regimen to switch them to another much cheaper regimen. Finally, the U.S. tentative approval process will not work for the newest medicines, including some important new proprietary fixed-dose combinations and some second-line therapies that will be crucial as patients develop drug resistance.

Thus, rather than join the existing multilateral process at the WHO, the U.S. is insisting on a unilaterally adding an unnecessary parallel process that will for all intents and purposes merely duplicate WHO approvals made many months earlier. Although this troubling process will be problematic in the short run, developing countries must adhere to the U.S. FDA-approval process when spending PEPFAR dollars. Hope fully in the long run, generic producers

will be willing to undergo both the WHO and the FDA process and incongruities between drug procurement requirements will lessen.

6. ECONOMIC ANALYSIS OF EFFICIENT GENERIC MANUFACTURE AND THE IMPORTANCE OF ECONOMIES-OF-SCALE

As discussed previously, developing countries have important incentives to develop their own indigenous capacity to manufacture pharmaceutical products. They can do so by encouraging a wide variety of entities, ranging from purely domestic companies to subsidiaries of multinational companies that site a relatively large facility within the country. Similarly, they can encourage local production that covers a wide range of productive activity varying from producers with innovative and manufacturing capacities of both active pharmaceutical ingredients and final formulations to producers that merely package already formulated medicines.[195] Developing countries can encourage this expanded capacity lawfully under TRIPS both by direct subsidy and by their own procurement preferences for pharmaceutical products manufactured locally. However, the allure of local production may blind some developing countries to its true cost. That cost may include decreased future flexibility to rely on Paragraph 6 Implementation Agreement importation options and the long-term payment of excessive prices for medicines that can be sourced much more cheaply from overseas.

In this regard, understanding the issue of economies-of-scale is vitally important. The United States has long understood the issue of advantageous economies-of-scale for its own pharmaceutical industry:

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195. The typology established by UNIDO (1980) differentiated production based on differences in the source of the finished product: (1) packaging of already formulated medicines and perhaps small-scale local production of formulations such as IV fluids; (2) formulation of drugs in final dosage form and perhaps some production from imported intermediates; (3) production from imported intermediates and manufacture of other intermediates from local materials, and (4) production of active substances and processing to produce the required dosage forms. An alternative typology differentiates (1) integrated corporations engaged in all stages of production and capable or generating new molecular entities for distribution through subsidiaries and licenses, (2) innovative companies typically producing off-patent medicines but capable of some innovation, and (3) reproductive firms that rely entirely on active pharmaceutical ingredients procured from others. Warren Kaplan, *"Local Production": Industrial Policy and Access to Medicines: An Overview of Key Concepts, Issues, and Opportunities for Future Research*, World Bank Meeting on the Role of Generics and Local Industry in Attaining the Millennium Development Goals in Pharmaceuticals and Vaccines, *available at* http://www.worldbank.org/hnp/hsd/documents/pharma_production.pdf (last visited Feb. 23, 2004).

The pharmaceutical manufacturing process, depending on the end product, includes chemical synthesis, fermentation, extraction of organic chemicals from vegetative sources or animal tissues, and formulation into dosage forms such as tablets, capsules, injectable solutions, ointments, etc. and packaging in bottles, blister packs, etc. *Id.* at 2.

> The foundation of free trade embodied in the WTO system is the removal of conditions that lead to inefficiencies in global trade. The WTO has long recognized the trade-distorting nature of local content, import substitution, and local production requirements. We note that the non-discrimination clause of Article 27.1 of the TRIPS Agreement is built on this foundation.
>
> Pharmaceuticals are among the best examples of products where these principles are true. Pharmaceuticals can be efficiently produced in a small number of locations and transported through international trade to markets needing those products. Such efficiencies of production and distribution lead to lower prices and faster supply of products to meet demands, including those caused by public health emergencies.[196]

Although the United States was trying to valorize its own proprietary drug industry with this statement and although there is little evidence that U.S. pharmaceutical monopolists have ever reduced their prices because of manufacturing efficiencies, economies-of-scale are demonstrably important to generic industries, as recognized by Canada in the EC-Canada pharmaceutical products case at the WTO.[197]

> Smaller countries that . . . have generic industries [do] not have domestic markets sufficiently large to enable those industries to operate on an economic scale. Those industries [have] to export in order to be able to manufacture in sufficient quantities to achieve economies-of-scale, so that domestic consumers [can] receive the benefits of cost-effect generic products.[198]

The efficiency concerns stated publicly by the United States and Canada confirm earlier studies that concluded that local production of pharmaceuticals did not make good sense for most developing countries because of diseconomies-of-scale and technological demands. The few exceptions were countries like China, India, Brazil, Thailand, Egypt, Mexico, Yugoslavia, Turkey, and Argentina that had large local markets and the ability to produce active pharmaceutical ingredients.[199] That number may have grown to include

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196. United States Statement at TRIPS Council Meeting, IP/C/M/31 (June 20, 2001).

197. Canada—Patent Protection of Pharmaceutical Products Complaint by the European Communities and their member States, Report of the Panel, WT/DS114/R (Mar. 17, 2000).

198. *Id.* ¶ 4.38(a).

199. Kaplan, *supra* note 195, at 5-6.

other countries with productive capacity such as South Africa. But, if the economic cost of creating local pharmaceutical capacity is excessive, if the quality of products is doubtful, or if the final pricing is not competitive with existing foreign generic manufacturers because of diseconomies-of-scale or otherwise, then "this 'local production solution' will be no solution at all."[200]

Moreover, developing countries will have to be willing to take a hard look at other factors affecting competitiveness including: a shortage of skilled labor; a weak financial sector; diminished flows of foreign direct investment; and other disadvantages facing smaller enterprises and smaller countries.[201] They will also have to consider the economic viability of single-drug facilities, for example, those that might primarily or exclusively produce fixed-dose combination ARVs.

Based on empirical research, Kaplan and others have concluded that:

> [t]here is a 'critical mass' of industrial and socioeconomic development and human and technical resources that must be reached before any 'indigenous' pharmaceutical industry can survive. These include:
> - GDP great than about $100 billion
> - Population greater than about 100 million
> - Sufficient numbers of the population enrolled in secondary and tertiary education
> - Competitiveness index (UNIDO) grater than about 0.15
> - A net position pharmaceutical balance of trade.[202]

These hesitancies about the economics of local production are compounded by additional concerns about quality assurance. As discussed in subsection 5.1, the issue of quality assurance is not just a function of good manufacturing practice, but also a function of quality control based on a functioning drug regulation and registration system, a functioning drug quality control laboratory, an efficient system for storing and transferring drugs, and an enforceable regime of drug legislation.[203]

Accordingly, there is considerable uncertainty about the ability of smaller developing countries to achieve efficiencies in drug manufacturing especially with respect to active ingredients and harder to formulate medicines. Some experts believe that only regional economies-of-scale can be achieved in sub-Saharan Africa and that South Africa is the only country

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200. *Id.* at 8.

201. *Id.* at 9.

202. Warren A. Kaplan et al., *Draft: Is Local Production of Pharmaceuticals A Way to Improve Pharmaceutical Access in Developing and Transitional Countries? Setting a Research Agenda*, (Apr. 23, 2003), *available at* http://www.worldbank.org/hnp/hsd/documents/LOCAL PRODUCTION.pdf (last visited Apr. 6, 2004).

203. *Id.* at 45.

with a reasonable chance to develop an African regional capacity.[204] Other experts, and indeed some countries assisting local production, appear to believe that smaller finishing plants can be efficient in making formulations and in labeling and packaging drugs for local consumption.[205] This debate is surely important to developing countries and they should investigate these issues very closely lest too many countries erroneously assume that each can become a major regional supplier. Moreover, developing countries should not lose sight of the importance of accessing standard quality, generic medicines at lowest cost thereby speeding and easing the flow of treatment to poor people bearing an unbearable burden of disease.

Whatever sourcing decisions they make, developing countries should seek to reduce barriers to generic entry and to generic companies achieving economies-of-scale. In order to invest in producing medicines efficiently, generic manufacturers need predictable markets, regulatory access, freedom from patent-infringement lawsuits, and relief from ancillary trade agreements that undermine their ability to sell standard-quality medicines cheaply. They also need *some* profit motivation.

7. NEGATIVE IMPACT OF EMERGING BILATERAL AND PLURILATERAL FREE TRADE AGREEMENTS ON POST-DOHA AND POST-PARAGRAPH 6 FLEXIBILITIES.

It would be gratifying to report that developed countries suffered a secure setback in their battle for TRIPS-plus intellectual property protections via the Doha Declaration and Paragraph 6 Implementation Agreement and that developing country solidarity and multilateralism had permanently restrained U.S. unilateralism. However, the persistence of the United States and other developed countries in pursuing the interests of their pharmaceutical industries has not yet ceased. Thus, at the same time that developed countries, led by the United States, were enacting a strategy of export containment in the WTO, the United States, in particular, was negotiating bilateral and regional trade agreement with greatly enhanced intellectual property protections.

To this end, in the past year the United States has concluded negotiations with Chile and Singapore and is negotiating further bilateral agreements with Morocco, Thailand, the Dominican Republic, Panama, and Australia. In addition, it is pursuing regional negotiations in Central America, the Andes, Southern Africa, and the entire Western Hemisphere. In each of these negotiations, the United States is seeking to impose TRIPS-plus intellectual property protections that would dramatically undermine both the Doha Declaration and the Paragraph 6 Implementation Agreement.

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204. *Id.* at 51.

205. *See, e.g.*, Bill Haddad, Chairman/CEO, Biogenerics, Inc, *Presentation*, World Bank Meeting on the Role of Generics and Local Industry in Attaining the Millennium Development Goals in Pharmaceuticals and Vaccines (June 23-24, 2003).

For example, even in Africa, at the heart of the AIDS pandemic, the USTR is undertaking trade negotiations to transplant U.S.-style patent protections into the South African Customs Union.[206] In order to meet "standards of protection similar to that found in U.S. law," SACU nations would be required:

- to limit compulsory licenses to national emergencies, to governmental, non-commercial use, and to anti-competitive practices remedies only;
- to bar parallel trade;
- to extend patent monopolies for administrative delays;
- to link drug registration rights to patent status;
- to enhance protections for clinical trial testing data by providing at least five years of data exclusivity, thereby precluding registration of medicines produced under compulsory licenses;
- to adopt criminal enforcement for patent violations, including improvidently granted compulsory licenses.

In sum, the proposed negotiation objectives would completely eviscerate the Doha flexibilities, dramatically increase IP protection, and reduce trade in affordable generic medicines.

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206. On November 4, 2002, United States Trade Representative Robert B. Zoellick formally notified Congressional leaders of the Administration's intent to initiate negotiations for a free trade agreement with the nations of the South African Customs Union: Botswana, Lesotho, Namibia, South Africa, and Swaziland. With respect to intellectual property rights, the negotiations would:

> — Seek to establish standards that reflect a standard of protection similar to that found in U.S. law and that build on the foundations established in the WTO Agreement on Trade-Related Aspects of Intellectual Property (TRIPs Agreement) and other international intellectual property agreements, such as the World Intellectual Property Organization Copyright Treaty and Performances and Phonograms Treaty, and the Patent Cooperation Treaty.
>
> —Establish commitments for SACU countries to strengthen significantly their domestic enforcement procedures, such as by ensuring that government agencies may initiate criminal proceedings on their own initiative and seize suspected pirated and counterfeit goods, equipment used to make or transmit these goods, and documentary evidence. Seek to strengthen measures in SACU countries that provide for compensation of right holders for infringements of intellectual property rights and to provide for criminal penalties under the laws of SACU countries that are sufficient to have a deterrent effect on piracy and counterfeiting.

USTR Resources, *Letter from Robert Zoellick to Senator Byrd, available at* http://www.ustr.gov/releases/2002/11/2002-11-04-SACU-byrd.PDF (last visited Feb. 25, 2004).

7.1 Export Limitations

More particularly, in the context of the production-for-export problem, the SACU and FTAA negotiations could be even more disastrous. For example, in the FTAA, the United States is the presumed sponsor of a troubling bracketed provision that would explicitly prohibit compulsory licensing for export (8.64 (6) (b)). In this regard, PhRMA has been very explicit that it is advocating this export ban in South Africa saying: "The USG should seek to limit the scope of Government use authority to exclude the possibility of Government use for the purpose of export, or for sale to the general public."[207] Basically, PhRMA and the USTR, by limiting compulsory licenses to national emergency and public non-commercial use, seek to prevent exports.[208]

If this no-export ban were to be imposed on SACU nations, then South Africa would be prevented from being a supplier of standard quality generic medicines to other SACU nations or to the subcontinent as a whole. If the ban were imposed on Brazil in FTAA negotiations, it too would be barred from becoming a regional supplier for generics in Latin America. Moreover, if the ban is imposed on Thailand in its bilateral negotiations, Asia would lose an important regional supplier. Since regional and international production-for-export of generic medicines is necessary for countries with little or no efficient manufacturing capacity, excluding one of the few technically competent Africa producers, all of the technically competent South America producers, and one of the more efficient Asia producers would be a huge blow to poor countries trying to import affordable generic medicines. Thus, any effort by U.S. free trade negotiators to sabotage pro-public health interpretations of TRIPS that would otherwise[209] permit the export of low-cost generic medicines is morally and legally unacceptable.

7.2 Data exclusivity and patent/registration linkage

Major drug companies and their champions in U.S. and E.U. trade offices are increasingly turning to data exclusivity and patent/registration linkage as their newest and sharpest tools for securing market hegemony. For example, in nearly all of its recent and pending bilateral and regional trade agreements, the United States is seeking data exclusivity for confidential drug

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207. PhRMA 2003 Annual 301 Report to the USTR, 71 (2003).

208. Exports would still be permitted where there has been a competition violation pursuant to Article 31(k) of the TRIPS Agreement.

209. The U.S.T.R.'s pursuit of heightened intellectual property rights is not limited to formal trade agreements. It has recently used its Special 301 Priority Watch List power against Guatemala, which thereafter passed stringent data protection legislation. Similarly, the U.S. required Cambodia to become TRIPS compliant in 2003 instead of 2016, as a condition of its entry to the WTO.

registration data that a company submits on a new drug entity, even when that entity is not itself separately patented. Once a country grants five years of data exclusivity on U.S. terms, generic producers are completely precluded from relying on the pre-existing data to establish the bio-equivalence of their medicines. Thus, in order to establish the quality, safety, and efficacy for purposes of registering a medicine for use, a generic company would have to duplicate time-consuming, expensive and ultimately unethical and wasteful clinical trials. Since it would not make sense to do so for time reasons alone—clinical trials ordinarily take 6-8 years to complete—data exclusivity spells a death knell to an effective import/export compulsory license scheme for the first five years that a new drug is on the market.

This five-year embargo is bad enough, but the United States is seemingly trying to totally eviscerate compulsory licensing schemes under even more recent provisions linking drug registration to patent status. For example, the recent CAFTA draft text, Chapter Fifteen Article 15.10.3 reads as follows:

> Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval in the Party or in another territory, that Party:
>
> (a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the product or its approved use during the term of that patent, unless by consent or acquiescence of the patent owner; and
>
> (b) if the Party permits a third person to request marketing approval of a product during the term of a patent identified as claiming the product or its approved use, it shall provide that the patent owner be informed of such request and the identity of any such other person.[210]

This provision, although it permits an application for registration during the term of a patent, requires notification of such application to the patent holder, who can thereafter make mischief for the applicant. Even worse precludes actual registration for marketing until patent expiration. Unless there is an implied limitation in the text to permit registration of medicines

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210. USTR, Central American Free Trade Agreement, draft texts, *available at* http://www.ustr.gov/new/fta/Cafta/text/index.htm (last visited Apr. 6, 2004).

produced under a compulsory license, the United States may have succeeded in euthenizing both the Doha Declaration and the August 30 Implementation Agreement in one fell swoop. Sure, countries can bypass patents, but then they confront new and insurmountable registration barriers that preclude registration for the remaining term of a patent, even after the five-year data exclusivity term has concluded! This outcome is not in any sense mandated by Article 39.3 of TRIPS, which only requires unspecified protection against "unfair commercial use."[211] Where a developing country has already determined that the public interest requires partial abrogation of a patent via a compulsory license, it is inconceivable there are not concurrent, just grounds for accessing confidential drug registration data to avoid the preclusive burden of repeat clinical testing.

In sum, there is a strong argument that the persistent effort by the United States to expand patent protections and data protection rules in the face of worst health crisis in the last six hundred years violates legal limits on U.S. trade policy[212] and an even stronger argument that it violates international human rights norms.[213] To counteract dangers implicit in the United States' continued pursuit of expanded intellectual property protections for its profit-bloated pharmaceutical industry, developing countries should unite to adopt a collaborative position resisting any efforts to add TRIPS-plus measures to the intellectual property provisions of regional or bilateral trade agreements. TRIPS, the Doha Declaration, and the Paragraph 6 Implementation Agreement should be seen as creating an impenetrable ceiling for intellectual property protections, particularly in the pharmaceutical sector. Only by uniting can developing countries resist being picked off one-by-one and region-by-region by U.S. trade negotiators.

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211. For an extended analysis of Article 39.3 and the options developing countries have to permit registration of bio-equivalent products, see Carlos M. Correa, *Protection of Data Submitted For the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement* (2002), *available at* http://www.southcentre.org/publications/protection/protection.pdf. (last visited Apr. 6, 2004).

212. These intellectual property negotiation objectives directly violate the principal negotiating objectives in the Trade Act of 2002, which requires the United States "to respect the Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization at the Fourth Ministerial Conference at Doha, Qatar on November 14, 2001." 19 U.S.C. § 3802(b)(4)(C) (2002). Similarly, by seeking TRIPS-plus provisions found in U.S. law, the U.S. Trade Representative is also directly violating Exec. Order 13155, 3 C.F.R. § 268.

213. Richard Elliott, *TRIPS and Rights: International Human Rights Law, Access to Medicines and the Interpretation of the WTO Agreement on Trade-Related Aspects of Intellectual Property,* Canadian HIV/AIDS Legal Network and the AIDS Law Project of South Africa (Nov. 2001), *available at* http://www.aidslaw.ca/Maincontent/issues/cts/briefs/TRIPS-human-rights-briefPDF.pdf (last visited Feb. 26, 2004).

8. THE SHORT-TERM MANDATE FOR ACCESS TO DRUG REGISTRATION DATA AND FOR AN ARTICLE 30 LIMITED EXCEPTION FOR ACCESS TO EXPORTED GENERICS AND A LONG-TERM MANDATE FOR EXPLORING ALTERNATIVES TO THE TRIPS AGREEMENT FOR MEDICINES.

A deep paradox of developed countries' trade policies and their persistent effort to maintain and expand the proprietary industry's hegemony in developing country markets is that these markets, where the AIDS, tuberculosis, and malarial pandemics are at their worst, comprise so little of the global pharmaceutical market. A frequent argument from the USTR and PhRMA is that intellectual property rights must be protected and even expanded to provide incentives for future research and development and that the interests of consumers in continued path-breaking medical discoveries is jeopardized if patent protections are not maintained worldwide. To rebut this false contention, one need only survey the current structure of the global drug market where the world pharmaceutical market in 2000 was estimated at $406 billion dollars. North America, the European Union, and Japan purchased eighty percent of that total, by dollar volume, and all of them have robust systems of patent protection that protect patent holders against generic competition. On the other hand, all of Africa, Latin America, and Asia, the so-called developing world, comprised only twelve percent of the global market in 2000 (despite having eighty percent of the world's population).[214] Sub-Saharan Africa, the center of the HIV/AIDS pandemic, comprises a miniscule 1.3% of worldwide drug sales and the poor countries of Asia and the Indian subcontinent only add another 3.9%.

Accordingly, pharmaceutical companies make the vast bulk of their profits on secure sales in rich countries that have strong protections for intellectual property rights. Moreover, drug companies earn a very handsome rate of return, on their sales—18.5%—which places them at the top of all U.S. industry groups, five times the all-industry average. As a result, the largest U.S. pharmaceutical concerns earned nearly $37 billion dollars in 2001, even after deducting expenses for current research and development. In sum, the pharmaceutical industry is remarkably profitable (and has been so for many years) and its ability to conduct future research and development is in no real jeopardy based on anything that happens to low-volume sales of some of its products in some developing countries facing compelling public health dilemmas.

However, even if the drug companies were not already making huge profits in rich countries, which is more than enough to fund future research and development, are they losing profits by preventing access to medicines in developing countries? To the contrary, tens of millions of poor people are

214. Kaplan et al., *supra* note 202, at 8-9.

going without access to affordable patented medicines, and drug companies aren't making a dime on those non-sales. How exactly are drug companies being hurt if someone else makes generic drugs much more cheaply, sells them to customers previously priced out of the market, and then pays a royalty, even a small one, to the patent holder, as they must under existing compulsory license rules? The worst that will happen to drug companies is that they might lose some highly profitable sales to a narrow spectrum of rich elites in developing countries if their market segmentation strategy fails. However, this "loss" is a small price to pay in order to dramatically increase access to life-saving medicines for the other 98% of the population in poor countries. Accordingly, PhRMA's intellectual property fundamentalism in developing countries produces little real benefit to shareholders or to consumers in developed countries.

As a result of coordinated global campaigns and activists' strategic focus on drug pricing and intellectual property barriers, the prices for antiretroviral therapy have plummeted in three and a half years from $10,439/year to $140.[215] As a result of those same campaigns, generic producers are now empowered to produce fixed-dose combinations, endorsed by the World Health Organization, that permit patients to take one pill twice a day rather than multiple pills at widely different times, thereby facilitating patient compliance and reducing drug resistance. Prices have plummeted because people imagined and believed that lives in developing countries are worth saving and worth fighting for. As a result, for the same amount of money that could buy branded and patented medicines for 20,000 rich people in Africa in 2000, the world can now buy generic ARVs for 2,000,000 Africans living with AIDS by 2005.

When unified in the aftermath of the anthrax scare, developing countries succeeded in overpowering the United States and producing the Doha Declaration. Now, they are letting the developed world juggernaut condition-alize recent advances to the point of rendering them difficult, if not impossible to achieve. Not only should they have rejected the Chairperson's draft statement, they should they have rejected the earlier Motta text as well. It contained too many compromises of vital public health interests and too many substantive and procedural inefficiencies. Developing countries would have done better to rely on the text of the Doha Declaration and the baseline flexibilities of the TRIPS Agreement. Then, willing generic producers could have exported under Article 30 of TRIPS (permitting limited exceptions to patent rights) to willing importers that have issued compulsory licenses. People living with treatable diseases need a full-size, fully operational Doha Declaration.

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215. In May of 2000 the combination of d4T/3TC/nevirapine was $10,439/patient/year. J. F. Wilson, *Building Africa AIDS Care From the Ground Up*, 139 ANN. INTERN. MED. 157, 157-60 (2003).

As a short-term solution to some of the most glaring defects in the current system for accessing cheaper generic drugs of assured quality, this article recommends two modest modifications of existing rules. First, with respect to data exclusivity and patent/registration linkage, WTO members should enact a permanent solution granting direct permission to access confidential drug registration data for the purposes of establishing bio-equivalence of a pharmaceutical product lawfully produced under TRIPS flexibilities, including new, if arthritic flexibilities under the Paragraph 6 Implementation Agreement.

ARTICLE 39 AMENDMENT

4. For purposes of implementing paragraph 3 above, a Member may nonetheless permit a subsequent registrant of a pharmaceutical product to compare its product against undisclosed test data, or, where authorized, against evidence of registration in another jurisdiction, in order to establish bio-equivalence of the product and thus its quality, safety, and efficacy of use. This permission may be limited to products lawfully produced pursuant to this Agreement or to any subsequent amendments, clarifications, or waivers thereof.

The second recommendation is that developing countries return to the bargaining table and undo the damage done by the Paragraph 6 Implementation Agreement and Chairperson's Statement. Instead of relying on a highly conditioned, limited, and procedurally burdensome Article 31(f) solution, developed countries should go back to the simplified approach they championed for so long and that was subsequently endorsed by the European Parliament, the WHO, and leading NGOs around the world—a limited exception under Article 30 of the TRIPS Agreement.

ARTICLE 30 PRODUCTION-FOR-EXPORT LIMITED EXCEPTION

Under Article 30 of the TRIPS Agreement and pursuant to Paragraph 6 of the Doha Declaration, manufacturing shall be allowed: (1) if the pharmaceutical product is intended for export to a third country that has issued a compulsory license for that product, or where a patent is not in force, (2) if there is a request to that effect by the competent public health authorities of that third country arising from a specified public health needs, (3) if that third country certifies that it has insufficient current capacity in its pharmaceutical sector to manufacture the medicines efficiently, and (4) if low-cost methods are utilized to differentiate the labeling and packaging of the product from the patented version.

Although this particular language may not be perfect, an Article 30 solution is vastly superior as an easy-to-use mechanism for getting quality-assured generics to developing countries in need. Having been forced into a strategic retreat by U.S. intransigence, developing countries should not solemnize an ineffective mechanism that locks in patent holders' prerogatives and lock outs the most cost-effective forms of generic production.

Despite these two essential short-term recommendations, tinkering with the TRIPS Agreement and trying to forestall even more draconian intellectual property protections affecting access to medicines may, in the long run, be an ineffective strategy. The TRIPS system was designed, fundamentally, to protect the interests of intellectual property industries in the Global North at the expense of poor consumers in the Global South. That is problematic enough when the product at stake is a form of entertainment or a fancy software package, but it is far more problematic when lives are at stake, as they are with respect to access to essential medicines.

Therefore, developing countries and their allies should consider alternatives to the intellectual property system both with respect to the development of medicines and to access. In this regard, treating medicines as global public goods is a particularly attractive theory. The public goods theory imagines that benign and well-funded public institutions can take over the supervision of research, development, and manufacturing of new drugs for neglected diseases and in addition supply large quantities of low cost medicines to poor consumers.[216] Although a detailed exploration of this and

216. *See* James Boyle, *Symposium, The Public Domain*, 66 DUKE J. LAW & CONT. PROBLEMS 33 (2003); James Love, *Benefits of a Treaty on R&D*, Session on Alternative Frameworks to Finance R&D, The Drugs for Neglected Diseases (DND) Working Group, Rio de Janeiro, Brazil (Dec. 3, 2002), *available at* http://lists.essential.org/pipermail/ip-health/2002-December/003797.html (last visited Jan. 31, 2004); Royal Society, *Keeping Science Open: The*

other alternatives to the patent and data exclusivity regime is well beyond the scope of this paper, it does behoove public health activists to imagine a world where medicines are not guarded by intellectual property rules that present nearly insurmountable barriers to pro-developing-country innovation *and* access. Despite the attractiveness of such an exploration, however, a long-term revolution in intellectual property rules offers little short-term solace for tens of millions of people living with diseases today that will kill them tomorrow. For these fellow world citizens, pragmatic battles in the thicket of existing rules must also be waged.

Effect of Intellectual Property Policy on the Conduct of Science (April 2003), *available at* http://www.royalsoc.ac.uk/files/statfiles/document-221.pdf (last visited Feb. 25, 2004); John Sulston, *The Heritage of Humanity*, LeMonde Diplomatique (2002), *at* http://mondediplo.com/2002/12/15genome (last visited Feb. 25, 2004) (discussing decisions not to patent the human genome). Certain elements of such an approach are underway. *See* Medecins Sans Frontieres Access to Essential Medicines Campaign and the Drugs for Neglected Disease Working Group, *Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases, available at* http://www.msf.org/source/access/2001/fatal/fatal.pdf (last visited Feb. 25, 2004); *Cf.* Luis Jodar, F. Marc LaForce, Constante Ceccarini, Teresa Aguado, Dan M. Granoff, *Menigococcal Conjugate Vaccine for Africa: a Model for Development of New Vaccines for the Poorest Countries*, LANCET, Apr. 1, 2003, *at* http://image.thelancet.com/extras/02art7254web.pdf (last visited Feb. 25, 2004).