



Tripping Over Health: U.S. Policy on Patents and Drug Access in Developing Countries

by Kimberly Ann Elliott and Carsten Fink

U.S. technological prowess can play an important role in promoting global development while simultaneously advancing American interests and prosperity. Achieving these goals depends on continued strong public support for innovation and adequate incentives for companies to invest in research and development (R&D). Intellectual property (IP) rights, such as patents and copyrights, provide protection against unauthorized copying and are therefore fundamental to creating a policy environment conducive for innovation. They add, in Abraham Lincoln's words, "the fuel of interest to the fire of genius."

In few sectors is the protection of intangible assets as important for private R&D as in the pharmaceutical industry. But this protection creates challenges for developing countries in two ways: by limiting access to needed products and by misaligning incentives for innovation. Poor people often cannot afford the high prices of patented medicines, and despite government support programs, there continues to be a large unmet need for pharmaceutical treatment of both infectious and non-infectious diseases throughout the developing world. And developing-country markets are too small to offer incentives for pharmaceutical companies to invest in R&D for diseases that primarily affect the poor. Developing a vaccine against malaria will never match the profits of creating, say, Viagra. What public-policy interventions can balance the need to encourage R&D with the need to provide medicines for poor people?

Navigating TRIPS and beyond

U.S. IP policies as they relate to developing countries have been neither consistent nor coherent. For more than two decades, they have tilted heavily in the direction of narrow commercial interests at the expense of broader public health objectives. Beginning in the 1980s, U.S. negotiators demanded that trade agreements include rules for IP protection. The most significant result was the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) at the World Trade Organization (WTO) which requires members, regardless of their level of development, to

eventually adopt and enforce laws providing minimum levels of protection to all forms of intellectual property. The provisions that raised particular concern require developing countries to adopt patent protection for pharmaceutical products, thereby reducing competition from off-patent (or "generic") drugs that the countries themselves could otherwise make more cheaply.

While there are provisions in the TRIPS rules designed to mitigate potential threats to public health, developing countries contemplating their use have faced U.S. political pressure not to do so. In bilateral agreements, where U.S. negotiators have greater leverage, they insisted until recently that even lower-income trade partners adopt IP protections comparable to those in the United States, with few of the flexibilities in TRIPS. Increasingly, the aggressive U.S. approach to protecting IP is coming under pressure from a variety of key players, including information technology companies, generic drug producers, and non-governmental organizations concerned about health problems in developing countries.

The next U.S. president should come down clearly in favor of a new policy that better balances public health needs in developing countries with private incentives for innovative activities. Part of what is needed is to use American ingenuity to create, expand, and strengthen mechanisms that spur and disseminate innovations to address public health problems in developing countries.

In particular, the next president should take the following three steps: (1) make clear through words and deeds that the United States supports the right of developing countries to use the flexibility provided in TRIPS to protect public health; (2) launch an international dialogue on burden-sharing in the financing of pharmaceutical research and development; and (3) increase support for initiatives seeking to promote R&D into diseases that primarily affect developing countries. These recommendations are discussed below.



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The White House and The World

Each day brings fresh evidence that Americans’ well-being is linked to the lives of others around the world as never before. Accelerating advances in technology and the creation of new knowledge offer undreamed-of opportunities. Yet global poverty, inequality, disease and the threat of rapid climate change threaten our hopes. How will the U.S. president elected in November 2008 tackle these global challenges?

The White House and the

World: A Global Development Agenda for the Next U.S. President shows how modest changes in U.S. policies could greatly improve the lives of poor people in developing countries, thus fostering greater stability, security, and prosperity globally and at home. Center for Global Development experts offer fresh perspectives and practical advice on trade policy, migration, foreign aid, climate change and more. In an introductory essay, CGD president Nancy Birdsall explains why and how the next U.S. president must lead in the creation of a better, safer world.

The White House and the World Policy Briefs present key facts and recommendations drawn from the book in a succinct form designed for busy people, especially senior policymakers in the executive and legislative branches of government. This brief is drawn from “Tripping Over Health: U.S. Policy on Patents and Drug Access in Developing Countries” by Carsten Fink and CGD senior fellow Kimberly Ann Elliott.

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Respect the flexibility in TRIPS for developing countries

Until recently, many developing countries did not provide patent protection for pharmaceuticals. Some, notably India, developed large domestic generic drug industries that competed with patent-holding multinational firms in those developing-country markets, helping to hold down prices. That changed with the Uruguay Round of trade negotiations, which included an agreement creating universal rules for protecting all forms of intellectual property. The provision that generated the greatest controversy required all WTO members to eventually provide twenty years of patent protection for inventions in all fields, including pharmaceuticals.

While all WTO members had to accept the same minimum standards, TRIPS provides substantial flexibility to developing countries in implementing them. For example, least-developed countries—though not other developing countries—can postpone the adoption of TRIPS-consistent patent rules until 2016.

Importantly, WTO members also retain the right to issue compulsory licenses—government authorizations to use patented products or technologies without the consent of the patent holder—as long as adequate remuneration is paid and reasonable efforts are made to obtain a voluntary license from the patent holder. However, the latter requirement can be waived in the case of national emergency or in the case of public non-commercial use—for example, providing medicines on a non-profit basis through public health clinics. To reiterate, it is the additional flexibility of not first negotiating with the patent holder to obtain a voluntary license that is restricted to national emergencies or public-use situations, not the authority to use a compulsory license itself.

In addition to the flexibility embedded in the original TRIPS agreement, a waiver to part of the agreement was adopted in August 2003. This waiver arose out of concern about a TRIPS requirement that production under a compulsory license should be predominantly for domestic use, which would have prevented countries without local production capacity, as in many poorer countries, from effectively using compulsory licenses. The waiver allows a country with generic production capacity, such as India, to seek a compulsory license at the request of a country without its own production capacity and then to export the needed medication to that country. The adoption of this waiver was only possible after concerted efforts by U.S. negotiators to narrow its scope were overcome.

Have countries used available TRIPS flexibilities? To some extent, the answer is yes. A number of countries have issued compulsory licenses in recent years, including Brazil, Eritrea, Ghana, Indonesia, Malaysia, Mozambique, Zambia, and

Zimbabwe. In addition, Rwanda in 2007 became the first country to notify the WTO of its intention to use the August 2003 waiver for the import of an antiretroviral drug from a Canadian generic manufacturer. These compulsory licenses were motivated by government concerns over high drug prices affecting the sustainability of public health programs, notably for treating patients living with HIV/AIDS.

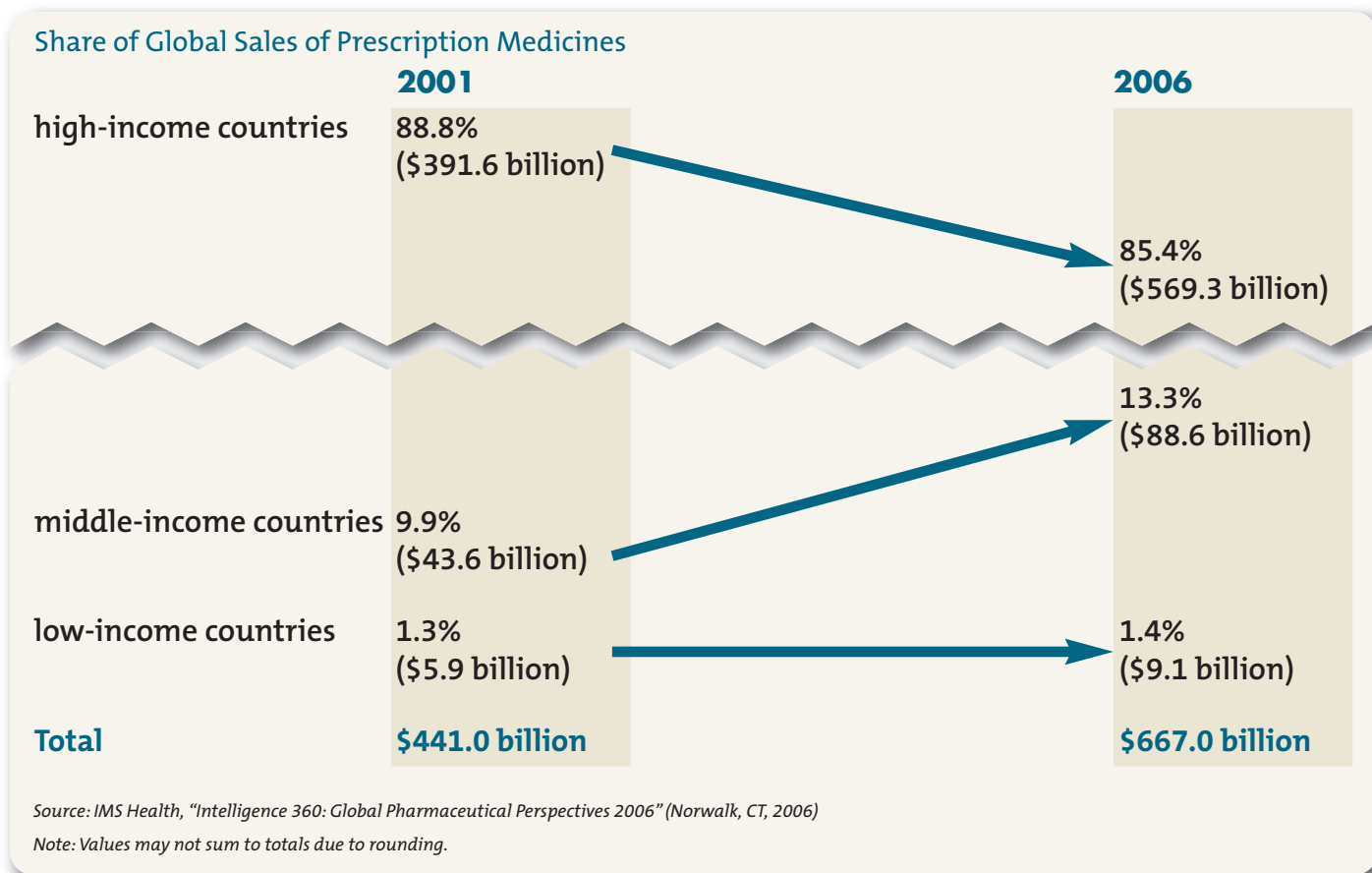
The U.S. government never challenged these compulsory licenses at the WTO, but it has put political pressure on countries not to grant such licenses and has sent ambivalent messages to countries that have done so. Most prominently, even though the U.S. Trade Representative acknowledged that Thailand's recent compulsory licenses for public use complied with WTO rules, it later elevated Thailand to the Priority Watchlist in its Special 301 Report, which identifies countries that may be subject to investigation and retaliation for insufficient protection of U.S. intellectual property.¹ And in a meeting with the Thai Health Minister, U.S. Commerce Secretary Carlos Gutierrez expressly demanded that Thailand abandon the issuance of the compulsory licenses.²

U.S. political pressure on compulsory licensing is not only inconsistent with developing countries' rights under the WTO, it is also hypocritical. For example, during the 2001 anthrax scare, some parts of the U.S. government advocated for granting a compulsory license on the antibiotic drug ciprofloxacin. In

addition, compulsory licenses are regularly granted in the United States as part of antitrust remedies. Most recently, the U.S. Supreme Court, in *ebay vs. MercExchange*, established that public interest must be taken into account in patent infringement cases. Thus, proven infringement may not automatically lead to the grant of a permanent injunction, but may well result in a compulsory license.³

Finally, the U.S. government has further undermined the flexibility provided in the TRIPS Agreement by negotiating stringent IP chapters in bilateral free trade agreements (FTAs). Since the end of the Uruguay Round, the United States has concluded FTAs with seventeen trading partners, including three awaiting congressional approval as of mid-2008.

While there is some variation, the TRIPS-plus provisions in FTAs have key elements in common. Most notably, U.S. negotiators generally seek to extend the length of the patent term to compensate for delays in regulatory approvals, to allow for patents for new uses of existing compounds, to limit the grounds for issuing compulsory licenses, to force drug regulatory agencies to play a role in enforcing patent rights even though they typically have no expertise in that area, and to create another layer of market exclusivity through rules for the protection of pharmaceutical test data, which further complicates the use of compulsory licensing.





After much international criticism, including from non-governmental organizations, for undermining developing countries' ability to address public health needs, the Democratic majority that took control of Congress after the November 2006 election insisted on changes that roll back the most damaging TRIPS-plus provisions (see box).

Determine appropriate burden-sharing for global innovation

The United States has a comparative advantage in many innovative and creative industries where IP protection is critical; it is natural that U.S. trade negotiators seek to protect that advantage. But IP standards involve a delicate trade-off between incentives for innovation and affordability of pharmaceutical products, a trade-off that depends on country-specific circumstances. Given lower patient incomes and fewer public resources devoted to healthcare, it is only natural for poorer countries to place greater emphasis on affordability. Even in the United States there is a vigorous debate about affordability of prescription medicines. In fact, both 2008 presidential candidates came out in support of importing patented medicines priced more cheaply in other developed countries—a move that would arguably cut into the profits of pharmaceutical companies and weaken R&D incentives.⁴

In this light, it seems hard to deny poorer countries the right to use the flexibilities of the TRIPS agreement and decide for themselves how the innovation-affordability trade-off is best addressed in a national context. That being said, uncoordinated IP policies raise a collective-action problem. Most developing countries are individually too small to materially affect the bottom-line of research-based pharmaceutical companies, but many middle-income countries are growing rapidly and as a group they could significantly impact profits (see table). Since developing countries benefit from new treatments against diseases affecting all countries, it is only fair—and indeed economically efficient—for at least the middle-income countries to share the burden of global R&D costs.

Current mechanisms for trying to resolve these dilemmas are ad hoc, uncoordinated, and potentially costly. Relatively large middle-income countries like Thailand and Brazil can withstand U.S. pressure and issue compulsory licenses, as provided under TRIPS, but smaller, poorer countries are often dependent on the charity of pharmaceutical companies or public or private donors. This has perhaps worked reasonably well for HIV/AIDS drugs, but it was Thailand's decision to issue a compulsory license for a heart disease treatment that triggered the most vehement reaction from drug companies and their supporters. And yet, it is increasingly the same

The “May 10 Agreement” on U.S. Bilateral FTAs

Since the approval of the North America Free Trade Agreement with Mexico and Canada in 1993, congressional Democrats have had growing concerns about the impact of such agreements with developing countries, particularly on U.S. workers and the environment. More recent is the concern about the impact of TRIPS-plus provisions on public health in the developing countries with whom we negotiate these agreements. When Democrats took control of Congress in 2007, they launched negotiations with the Bush administration to address all of these concerns. On May 10, 2007, they agreed to changes on labor, environment, IP protection, and a few other issues that are to be incorporated in pending FTAs.

Among other things, the May 10 agreement calls for a patent-term extension that compensates for delays in obtaining marketing authorization to now be voluntary. Similarly, drug regulators would not be required to deny marketing approval based on a drug's patent status, provided that there are other means for patent holders to assert their rights. Crucially, the agreement removes provisions that could have blocked the ability of countries to make effective use of compulsory licensing.

The immediate impact of the bipartisan trade deal is limited, as it applies only to the FTAs negotiated with Peru, Colombia, and Panama (assuming the latter two are approved by Congress). However, the deal could mark an important political shift in U.S. trade policy toward greater sensitivity to public health concerns in global IP rules—a shift that offers the incoming president a basis on which to put forward a more coherent set of policies.

chronic diseases, like heart disease and diabetes, that affect health in rich countries that are afflicting developing countries.

To address the situation, the next U.S. president should initiate a dialogue to explore how global R&D costs could be better shared among nations, especially with middle-income countries that are too rich to make no contribution but too poor to pay rich-country prices. Such an international dialogue would arguably help reduce conflicts on IP protection, as developing countries would be less compelled to resort to compulsory licenses to ensure affordability. It should also be in the best interest of the United States, which bears the largest burden of global R&D and has substantial domestic healthcare concerns about high drug prices.

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Support R&D into developing-country diseases

The incoming president should also scale up U.S. support toward promoting more R&D into diseases that primarily affect developing countries. Even if patents were strongly enforced throughout the world, there would be little commercial incentives to invest into these lines of R&D, as the poorest countries account for only a tiny share of global pharmaceutical sales. Government or donor intervention is necessary. This could occur through altering patent laws to encourage R&D for developing-country diseases, or through direct financing of pharmaceutical R&D or incentive-based mechanisms. Examples are advance market commitments or innovation prizes, whereby the public or charitable sector creates an incentive for private pharmaceutical companies to conduct R&D. An opportunity to demonstrate how this works is the recently created advance market commitment for a vaccine to prevent the strain of pneumococcal disease that is prevalent in poor countries.

Conclusion

In sum, the president taking office in January 2009 has the opportunity to rebuild America's reputation as a benign rather than malign hegemon by adopting a new policy on trade and IP. First, the president should reverse the policy of pushing for stronger IP protection in developing countries and respect their right to use the flexibilities provided under TRIPS, including the use of compulsory licenses. Second, he should initiate an international dialogue on how the global pharmaceutical R&D burden can be shared more fairly and efficiently. Finally, U.S. leadership should aim to promote and scale up schemes to spur innovation on treatments for diseases that mainly affect poor people in developing countries.

Endnotes

¹ See the letter by Susan Schwab to Congressman Thomas Allen, January 17, 2007, and the 2007 USTR 301 Report.

² "Drop Drug Policy, U.S. Tells Thais," *Bangkok Post*, May 23, 2007.

³ "Special Patent Pleadings," *Financial Times*, April 21, 2008.

⁴ See <http://www.barackobama.com/issues/healthcare/> and <http://www.johnmccain.com/Informing/Issues/19ba2f1c-c03f-4ac2-8cd5-5cf2edb527cf.htm>.

Further Reading

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