Congress of the United States

Washington, DC 20515

March 12, 2007

The Honorable Susan Schwab
United States Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Dear Ambassador Schwab:

According to international health organizations, ninety percent of the 14 million people killed annually by treatable infectious disease live in the developing world. Even more die of treatable noninfectious illnesses. But despite the high disease burden in developing countries, one-third of the world's population has no access at all to essential medicines. The need for expanded access to affordable drugs is dire, and demands careful attention when international trade policies address intellectual property.

Recognizing this, the U.S. was one of 142 countries that adopted the 2001 "Doha Declaration" on the Trade-Related Aspects of Intellectual Property Agreement (TRIPS) and public health.[1] The Doha Declaration "reaffirm[ed] the right of WTO members to use, *to the full*, the provisions of the TRIPS agreement which provide flexibility" to protect public health.[2] It specifically affirms countries' rights to interpret and implement trade obligations in ways that protect access to essential medications.[3] In the 2002 Trade Promotion Authority Act, Congress directed the Administrative branch to adhere to the Doha Declaration as a "principal negotiating objective" in U.S. trade negotiations.[4]

Regrettably, recent U.S. free trade agreements (FTAs) appear to undermine this commitment with provisions that strip away flexibilities to which countries are entitled under TRIPS. The FTA provisions also appear to upset an important balance between innovation and access by elevating intellectual property at the expense of public health. The end result is that they threaten to restrict access to life-saving medicines and create conditions where poor countries could wait even longer than the United States for affordable generic medicines.

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[1] *Declaration on the TRIPS Agreement and Public Health*, WTO Ministerial Conference — Fourth Session, WT/MIN(01)/DEC/2, adopted 14 November 2001 ("Doha Declaration") (online at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm); World Trade Organization, *Agreement on Trade-Related Aspects of Intellectual PropertyRights* (1994) ("TRIPS") (online athttp://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm).

[2] Doha Declaration, Paragraph 4 (emphasis added).

[3] *Id.*

[4] Pub. L. No. 107-210; 19 U.S.C. §3802(b)(4)(C).

We are writing to urge the immediate reconsideration of these provisions in recently negotiated FTAs with Colombia, Peru, and Panama, and in pending agreements with Thailand, Malaysia, and others.

Our concerns are detailed below.

Data Exclusivity

Under WTO rules, pharmaceutical innovations receive twenty years of patent protection.[5] Recent U.S. FTAs add an additional requirement: a period of "data exclusivity" that begins when a patented drug receives marketing approval.[6] During this period, regulators cannot rely upon clinical test data submitted for a drug's first approval when considering marketing approval for generic versions. The effect can be to delay the availability of generics even if a patent has already expired.

Current U.S. law provides data exclusivity, but places strict caps on the periods available.[7] In contrast, the recent FTAs require data exclusivity periods but do not require caps.[8] As a result, developing countries may face pressure to adopt longer exclusivity periods, presenting a scenario where the wait for generics could be even longer in a developing country than in the United States. Even if a developing country institutes limits equal to those in the United States, the wait for generics could still be longer if a company launching a new medicine in the United States does not seek approval in the developing country until later.[9]

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[5] TRIPS, Article 27.1 and Article 33.

[6] See, e.g., Peru FTA §16.10.1; Colombia FTA § 16.10.1; Panama FTA §15.10.1.

[7] 21 U.S.C. §355(j). The current U.S. framework for the approval of generics was established by the *Drug Price Competition and Patent Term Restoration Act,* Pub. L. No. 98-417 (98th Congress, 1984). This legislation is also known as the "Hatch-Waxman Act."

[8] The FTA texts use the term "at least" in regard to the 5-year period of exclusivity. (See *supra* note 6).

[9] The FTAs with Central America and Panama let drug companies wait up to five years after launching a drug in the U.S. to launch it in the other nations, and still get five years of marketing exclusivity upon approval in each country. As a result, approval of a generic for these FTA partners could lag up to five years behind general approval in the U.S. (CAFTA, §15.10.1(b) and Panama FTA §15.10.1(b)).

The data exclusivity provisions ignore fundamental differences between the development of U.S. law on generics and the context of today's trade agreements. When periods of marketing exclusivity were introduced in the United States, there were few generics on the market. The exclusivity periods were coupled with measures to facilitate the approval of generics and accelerate competition in the marketplace. In contrast, today many countries have access to a competitive generic market. Data or marketing exclusivity does not improve generic access in these countries, and creates the potential for serious harm.

For any patient, five years or more without a medicine priced out of reach can be severe. The consequences are especially serious for patients with HIV/AIDS or other chronic diseases, where the cost of treatment can mean the difference between life and death. Colombia and Peru, parties to recently negotiated U.S. FTAs, together have more than a quarter million people infected with HIV and alarmingly low treatment access rates.[10]

Patent Extensions and "Linkage"

Another obstacle presented by the FTAs is the provision for potentially unlimited patent extensions. U.S. law grants patent extensions when there are delays in either the patent review or marketing approval period, but safeguards consumer rights by limiting the total duration permitted.[11] The FTAs require that countries provide patent extensions for such delays – but do not require any limitations.[12] Because developing countries have scarce resources for these activities, the review and approval processes can be lengthy. With the resulting extensions, the patent term could be longer in a developing country than in the United States.

Further, the FTAs place an onerous "linkage" between drug approval and patent authorities.[13] A typical example is the requirement that a drug regulatory authority withhold approval of a generic drug until it can certify that no patent would be violated. Such provisions put a significant burden on regulatory agencies that have neither the expertise nor the authority to enforce private patentholder rights. The problem is especially severe for developing countries

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[10] UNAIDS, *Countries* (online at http://www.unaids.org/en/Regions_Countries/Countries/default.asp).

[11] 35 U.S.C. § 156. In the United States, patent extensions in cases of approval delay are limited in the following ways: (1) only one five-year extension is permitted; (2) the extension applies to only one patent per product; and (3) the total life of a patent from the time of marketing approval cannot exceed 14 years.

[12] See, e.g., Peru FTA §16.9.6.; Colombia FTA §16.9.6; Panama FTA §15.9.6.

[13] See, e.g., Peru FTA §16.10.3(a); Colombia FTA §16.10.3(a); Panama FTA §15.10.2(a).

where resources are already stretched thin by the primary task of monitoring the safety, efficacy, and quality of medicines on the market. The provision could compromise this fundamental mission and cause indefinite delays for the approval of generic drugs.

Compulsory Licensing

Compulsory licensing is the government granting of a license to a manufacturer other than the patentholder to produce a drug at an affordable price. The Doha Declaration affirmed the TRIPS principle that each WTO member country has "the freedom to determine the grounds upon which such licences are granted."[14] However, the U.S. has included provisions in FTAs to narrow these grounds.[15]

USTR has also refused to reference the right to compulsory licensing - or other public health exceptions - in the text of FTAs. Instead, USTR has relied upon the use of vaguely worded "side letters" that are subordinate to the agreements and non-binding on the parties. The letters also fail to provide clear and specific assurances affirming the ability of governments to take various measures to address public health needs.[16]

Absence of Appropriate Consumer Safeguards

Certain key elements of U.S. law designed to protect consumer access are entirely left out of the FTAs. These include:

- The Bolar provision, a law allowing the early registration of generics so that they can enter the market promptly once a patent expires.[17]

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[14] Doha Declaration, Paragraph 5(b).

[15] For example, the Singapore agreement sets three narrow conditions under which compulsory licenses will be permissible. Under this agreement, a compulsory license will only be allowed: (1) if a court determines that the patentholder engaged in "anti-competitive" behavior; (2) when a government agency or contractor needs to use the patent; or (3) in a "national emergency or other circumstances of extreme urgency." (Singapore FTA §16.7.6). The Agreement also provides that a patent owner subject to a compulsory license under condition (2) or (3) cannot be required to transfer "technical know how" to the licensed generic manufacturer. (Singapore FTA §16.7(b)(iii)).

[16] See, e.g., U.S.-Colombia FTA:"Understanding Regarding Certain Public Health Measures" and "Letter Regarding Certain Regulated Products," signed November 22, 2006.

[17] 35 U.S.C. § 271 (e)(1).

- A requirement that patent applicants describe the "best mode" to reproduce an invention.[18]
- Protections to address attempts to gain repeated and unjustified patents on a product.[19]

The absence of these safeguards further threatens access to affordable generics in poor countries.

Conclusion

The world's consensus at Doha was that all nations have the right to use the flexibilities available under TRIPS to "promote access to medicines for all." Protecting innovation is important, but the intellectual property provisions in current FTAs extend pharmaceutical monopolies without sufficient regard to consumer access and public health.

We call on you to pursue a trade agenda that reasserts the U.S. commitment to the Doha principles, and to revise the FTAs now under consideration.

Sincerely,

Henry A. Waxman
Member of Congress

Jim McDermott
Member of Congress

Tom Allen
Member of Congress

Lloyd Doggett
Member of Congress

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[18] 35 U.S.C. S § 112.

[19] U.S. law provides mechanisms to counter the abusive "evergreening" of patents, by which patentholders might use minor changes or frivolous patents attempt to gain repeated and unjustified patent protection for a pharmaceutical product. For example, U.S. law limits the types of patents that relate to generic approval, and includes a specific mechanism for patents to be challenged. (See *supra* note 7).

Janice D. Schakowsky
Member of Congress

Pete Stark
Member of Congress

Diana DeGette
Member of Congress

Chris Van Hollen
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Barbara Lee
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Earl Blumenauer
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