

# Drug company patents and “Fast Track”: *U.S. trade policy must prioritize access to AIDS medicines*

**BACKGROUND:** Patents monopolies prohibit competition from generic drug manufacturers. This is of particular concern in developing countries where millions of people with AIDS live on less than a dollar a day. For example, when a drug patent expires in the U.S., and multiple generic producers enter the market, the price can drop by as much as 80%.<sup>1</sup> Even though countries are allowed, per World Trade Organization (WTO) rules, to break patent monopolies, wealthy countries like the United States, working with pharmaceutical companies, historically have bullied countries that tried to use that leeway in order to drive the cost of medicine down.

The WTO requires all member countries to follow the rules set out in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The agreement requires countries to protect intellectual property rights (IPRs), including granting at least 20-year patents on essential goods like medicines. But, due to push-back from poor countries, at the third WTO Ministerial meeting in Doha, Qatar, WTO members promised to allow countries to prioritize the health needs of their citizens when implementing IPRs. Countries are allowed, according to the WTO, to “break” patents and produce life-saving medication generically if it is in the interest of the health of its citizens. In recent months, Brazil and Thailand have taken advantage of this flexibility to lower the cost of medicine in their country.

For millions of people with AIDS in developing countries, the price of medicines is still too high for most people to afford. This is true specifically for the price of newer, more effective AIDS medicines that are still protected by patent monopolies. For people in poor countries who need these medications, the impact of the patent barriers created by WTO rules are life-threatening.

**THE DOHA DECLARATION:** At the WTO Doha Ministerial Meeting in November 2001, AIDS activists, developing country governments, and other allies forced the WTO to begin to correct this imbalance between the rights of poor people to access lifesaving drugs, and the commercial interests of pharmaceutical companies.

The Doha Declaration on the TRIPS Agreement and Public Health (the “Doha Declaration”), signed on November 14, 2001, states that TRIPS can and should support “WTO members' right to protect public health and, in particular, to promote access to medicines for all.” The Doha Declaration also reaffirmed WTO members’ right “to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility” for the purposes of promoting public health and access to medicines for all.<sup>2</sup>

Thailand and Brazil’s recent decision to issue licenses for generic production of important patented AIDS drugs like efavirenz and lopinavir/ritonavir are examples of countries using the flexibilities that were reaffirmed by the Doha Declaration, and that are completely lawful under the TRIPS Agreement.



<sup>1</sup> Food and Drug Administration, Center for Drug Evaluation and Research (CDER). “Generic Competition and Drug Prices.” April 4, 2006. [http://www.fda.gov/CDER/ogd/generic\\_competition.htm](http://www.fda.gov/CDER/ogd/generic_competition.htm) Accessed May 3 2007.

<sup>2</sup> Available at: [http://www.wto.org/English/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_trips_e.htm)

**THE BUSH ADMINISTRATION BREAKS ITS PROMISE:** In response to the WTO's affirmation of the right of countries to prioritize access to medicines ahead of the profits of pharmaceutical companies, the Bush Administration accelerated trade negotiations with individual countries and groups of countries, signing trade agreements that impose new requirements on countries to protect drug company patents. These new trade agreements disregard the Doha Declaration and exceed the standards for protection of intellectual property rights in the TRIPS Agreement. A recent study of the impact of the U.S. Jordan Free Trade Agreement shows that the "TRIPS-plus" provisions of that agreement have increased the cost of medicines, with none of the benefits promised.<sup>3</sup>

**PUTTING THE BREAKS ON "FAST TRACK":** The Bush Administration has been able to sign and implement trade agreements that require countries to trade away their right to health because the current Congress has no ability to amend trade agreements. Congress is only permitted a yes-or-no vote. Trade Promotion Authority (TPA, also called "Fast Track") is the law that cedes Congressional power over trade to the President—Fast Track expired July 1, 2007, and is not expected to be renewed during the rest of President Bush's term.

**CURRENT NEGOTIATIONS AND "THE NEW DEAL":** The issue of public health and access to medicines is at the center of current Congressional debates on U.S. trade policy. For example, negotiations between Democratic Congressional leaders and the United States Trade Representative (USTR) over trade agreements with Peru and Panama have resulted in limited changes that have mitigated a small amount of the harm of the intellectual property provisions in those two agreements.

These changes are very small, initial steps toward a U.S. trade policy that allows countries to prioritize public health and access to medicines. But more substantive changes that will actually result in increased access to medicines in developing countries will only come if lawmakers are pressured to support and fight for those changes. For example, the current deal between Democrats and the USTR still requires countries to grant a period of exclusive rights to pharmaceutical companies over data generated by studies they perform on the medication—this is a huge gift to pharmaceutical companies, it is not required by TRIPS, and it delays the market entry of cost-cutting generics.

**OUR NEXT PRESIDENT MUST PUT PEOPLE BEFORE PROFITS:** The next president of the United States must support a positive trade agenda which not only does not prohibit countries from using the flexibilities allowed by the WTO to break patents and produce low-cost generic drugs – **our new trade policy must promote access to medicine** by providing incentives for countries to break patents. US policy must not effectively extend monopolies beyond the original 20 years by allowing for data exclusivity (DE). DE prohibits the data from the clinical trial that showed a medicine is effective from being used to prove that a generic version of the same medicine is also effective (generic companies are normally not required to repeat clinical trials). This data is essential for generic manufacturers to have if they are to get approval to sell their drug, and protections of the data can result in extensions of monopolies beyond patent terms because generic manufacturers can't get approval for their drugs without the clinical trials data to prove the drug is effective. DE has been standard in trade agreements negotiated by President Bush under Fast Track, but newer agreements negotiated with input from House Democratic Leadership have reduced the harm of these provisions in developing countries by limiting the term of DE to the five years that drug companies are granted exclusivity in the US.

**TAKE ACTION:** By pressuring lawmakers, presidential candidates, and other influential decision makers to support alternatives to the current U.S. trade policy, we can win major changes that ensure countries can use public health flexibilities to increase generic competition, drive down medicine costs, and increase access to medicine in developing countries.

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<sup>3</sup> "All costs, no benefits: how TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines." 21 March 2007. [http://www.oxfam.org.uk/what\\_we\\_do/issues/health/bp102\\_trips.htm](http://www.oxfam.org.uk/what_we_do/issues/health/bp102_trips.htm) Access March 24 2007.