



The Trans-Pacific Partnership Agreement (TPP) threatens access to affordable medicines

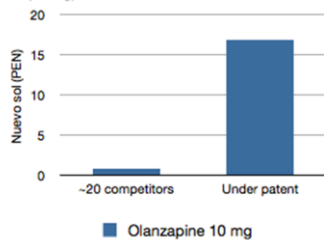
The Trans-Pacific Partnership Agreement (TPP), a proposed trade deal between 12 Asia-Pacific countries including the United States, would increase costs for national health programs and over time jeopardize many and perhaps millions of lives in the Pacific region. In the Doha Declaration of 2001, all World Trade Organization (WTO) members—including the U.S.—acknowledged the humanitarian costs of pharmaceutical monopoly

Among the most damaging concessions developing countries make in regional and bilateral agreements are those enhancing the monopolies on life-saving medicines, which reduce access and affordability and those that provide excessive legal rights to foreign investors, limiting the policy space for nations to promote sustainable and inclusive development.
--H.E. Archbishop Silvano M. Tomasi, Apostolic Nuncio, Permanent Observer of the Holy See to the United Nations and Other International Organizations, December 2013

rights and agreed that patent protections should not block access to affordable medicines or interfere with countries' public health agenda. But provisions in the TPP would expand patent monopoly rights, limit flexibilities, and facilitate abuse of the patent system. Longer, broader, and stronger monopolies mean reduced generic competition and higher drug costs for families and national health programs.

How will the TPP affect access to medicines?

Price comparison of Olanzapine (10mg) with and without patent protection, Peru



Olanzapine is a treatment against schizophrenia and mental illnesses. In 2008, in a market with 20 competitors, the treatment cost 0.79 PEN per tablet. After the patent holder enforced its patents against competitors, the cost reached 16.95 PEN per tablet, more than 21 times the price under competition.

When a drug is under patent, generics, which can cut costs by 30-80%, cannot be brought to market. Under WTO rules, pharmaceutical companies can obtain 20-year patents for inventions that are new and non-obvious. But the TPP will enable pharmaceutical companies to: 1) extend their patents beyond 20 years, 2) re-patent medicines that are already known and thus, are not necessarily inventions, and 3) block the registration of generic products. The longer a product is under patent protection, the longer patients have to wait for low-cost versions of the patented drugs. Such delays lead to preventable suffering and death.

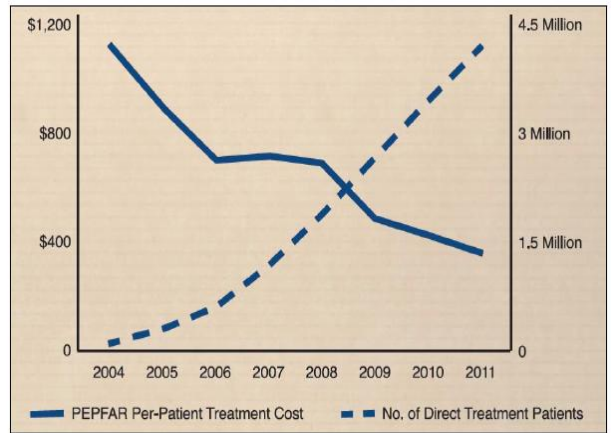
If brand-name companies obtain expanded monopoly rights for pharmaceuticals through the TPP, generics manufacturers worldwide will have reduced market opportunities in TPP countries and therefore fewer incentives to produce affordable lifesaving treatments such as cancer drugs. The lost economies of scale could limit the global competition needed to help make medicines affordable for a majority of the world's people.



TPP's IP measures could burden PEPFAR

The President Emergency Plan for AIDS Relief (PEPFAR) relies heavily on the availability of generic anti-retroviral treatments (ARVs) which are many times cheaper than originator brands to reach treatment goals. In 2010, 97% of all ARVs purchased by PEPFAR were generics. However, when a treatment is patented, PEPFAR is obliged to procure brand-name products at much higher costs. For instance, in Vietnam, PEPFAR is facing challenges providing access to second-line HIV/AIDS treatments due to patent protection. New restrictions on generic competition through the TPP would provide companies with additional opportunities to block or delay the availability of low-cost generics thereby increasing costs, limiting efficiency, and potentially preventing PEPFAR from reaching treatment goals.

Figure A-1. PEPFAR Per-Patient Spending on ART, 2004-2011
(current U.S. dollars and millions of people)



Source: Department of State, PEPFAR Saving Lives Infographic, Fact Sheet, July 2012, <http://www.pepfar.gov/documents/organization/195545.pdf>.

PEPFAR's Vietnam Operational Plan Report FY 2010

"Second-line generic medicines ... are still nearly 10 times the cost of first-line medicines. A key driver is the cost of Abbott Lopinavir/Ritonavir products. Expectations that the cost of Lopinavir/Ritonavir would fall by 50% in 2009 due to the introduction of generic versions were dashed when it was discovered that Abbott has patents pending in Vietnam and that Abbott intended to use the patents to prevent the procurement of generic alternatives."

TPP imposes requirements for developing countries beyond May 10 Agreement

On May 10, 2007, the Bush Administration and Democratic leaders in Congress reached a trade deal that began to reduce the harmful effects of U.S. trade agreements on access to medicines in developing countries. U.S. trade policy today should build on this progress. Instead, the TPP would oblige developing countries to implement harsher provisions that compromise access to medicines. The only safeguard the Obama Administration has proposed would limit the applicability of three TPP provisions to countries below a certain per capita income. But at least two developing countries in the negotiations are likely to cross this threshold in the near future. In addition to losing the very modest health protections of the May 10 Agreement, these countries—and all TPP countries—would also have to implement new harmful measures, including data exclusivity for biologics (i.e. new cancer medicines), patents for medical procedures, and second-use patents.

Provisions required in TPP	May 10 Agreement	Impact
Patent term extensions	Optional	Patent monopolies last beyond 20 years and delay market entry for generics.
Patent-registration linkage	Optional	Even bad or overly broad patents can block generic drug registration.
Data exclusivity (DE)	5 years of DE not longer than U.S.	At least 5 years DE for new products + at least 3 more years for new uses of existing medicines. Confers monopolies even where this is no patent.
Extra-long exclusivity for biologics	No provision	Precludes access to affordable cancer treatments and other new biotech medicines in some cases beyond patent expiration.
Second-use patents	No provision	Brand-name companies can re-patent old medicines—ever-greening.
Patents for medical procedures	No provision	Medical providers may have to pay royalties for use of patented methods of treating patients.



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