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Briefing Memo

Leaks at Trans-Pacific Trade Talks Confirm Obama Administration Backtracking from Bush Era Access to Medicines Commitments

Four Years After FTA, US Demands New Concessions, Law Changes From Peru

October 22, 2011

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LIMA, PERU – New leaked texts proposed by the United States to the Trans-Pacific Free Trade Agreement (FTA) show that the Obama administration has again increased demands on developing countries to trade away access to medicines. The new leaked proposals on intellectual property roll back even modest Bush era commitments to safeguard public health in trade pacts.

If adopted, the US texts would restrict generic competition and raise medicine costs, compromising access to needed medicines for people throughout the Asia-Pacific region. The US proposal would lengthen and create new pharmaceutical monopolies, grant additional exclusive controls over clinical trial data and eliminate safeguards against patent abuse.

The new leaked texts would also alter the trade deal Peru struck with the US only four years ago. The proposed text would change Peruvian law and force Peru into conflict with the Andean Community and its Common Intellectual Property Regime. The provisions proposed by the US are highly controversial in Peru. The failure of tariff reductions to translate into lower medicines prices for consumers was a front page scandal in Peru this year. In the lead up to this week's ninth round Trans-Pacific FTA talks in Lima, Peru's trade minister Jose Luis Silva told journalists that Peru will give "not one centimeter more" on health and trade.

The new leaked US proposals on intellectual property, pharmaceutical formularies (annex to the transparency chapter), technical barriers annexes on pharmaceutical products, cosmetics and medical devices, as well as draft text on draft regulatory coherence, are *available at*: www.citizenstrade.org.

Public Citizen has analyzed the changes that U.S. patent proposals to the Trans-Pacific FTA would require of Peruvian law, and how these changes could affect access to medicines. This analysis is *available at*: <http://citizen.org/peru-Trans-Pacific-FTA-chart>.

Specifically, the US proposal would:

- **Expand pharmaceutical patenting and create new drug monopolies**, by requiring patentability of new uses and minor variations of older, known drugs.
- **Lengthen drug monopolies** by requiring countries to extend patent terms depending on the time needed for patent prosecution or marketing approval (and in some cases provided the patent holder does not fail to bring its product to market within an as-yet unspecified period – the so-



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- called “access window”). Patent term extensions significantly delay the market entry of generic drugs, and thus access to affordable medicines.
- **Eliminate safeguards against patent abuse**, including the right of third parties to challenge patent applications (pre-grant opposition).
 - **Risk facilitating patent abuse** by requiring countries to condition marketing approval on patent status (patent linkage). Under patent linkage, even spurious patents may function as barriers to generic drug registration.
 - **Extend exclusive control over clinical trial data** including through an extra three years of data exclusivity for new uses of known products (in addition to five years exclusivity for first uses).

Public Citizen's analysis covers each of these items in further detail: <http://citizen.org/peru-Trans-Pacific-FTA-chart>.

The US text also includes an implicit attack on global efforts to increase access to medicines for Non-Communicable Diseases (NCDs). The text notably omits NCDs from a list of circumstances for which the US admits countries' rights to use public health flexibilities in patent rules.

The Office of the United States Trade Representative has made much of its proposed “access window,” which grants especially strong exclusive rights (patent term adjustment, linkage and data exclusivity) to companies that bring products to market within the as yet unspecified period. Unfortunately, the leaked text shows that under the access window and US proposal, monopoly privileges for patent holders would increase over the Peru FTA standards, limiting generic competition and compromising access to medicines.

The Office of the U.S. Trade Representative recently sought to quiet controversy over its aggressive trade texts by proposing an interagency initiative on Trade-Enhancing Access to Medicines, or TEAM. Unfortunately, the leaked texts suggest that the TEAM initiative masks a larger effort to entrench drug product monopolies.

For more information, see: <http://www.citizen.org/more-about-trans-pacific-FTA>.