Intellectual Property in the Trans-Pacific Partnership

How the TPP Endangers Access to Medicines in Peru

Peru and the United States are currently negotiating a new free trade agreement, the Trans-Pacific Partnership (TPP), with nine other countries in the Asia-Pacific region (Australia, Brunei Darussalam, Canada, Chile, Malaysia, Mexico, New Zealand, Singapore and Vietnam). According to leaked texts, the United States is pushing for aggressive measures that go beyond the US-Peru free trade agreement (FTA) and further endanger access to affordable medicines against cancer, heart disease, and HIV/AIDS, among other conditions.

The United States has proposed TRIPS+ and US-Peru FTA+ terms that would transform Peru's laws on patents and clinical trial test data and attack government purchasing and medicine formularies. These provisions would further limit generic competition and raise pharmaceutical prices, thereby restricting access to affordable medicines. The same provisions would hinder local pharmaceutical production and innovation in Peru.

The U.S. proposal would:

- **Greatly expand patent scope and promote "ever-greening"**
- **Require patent protection for methods of treating patients**
- **Further delay access to affordable generic medicines**
- **Risk facilitating patent abuse**
- **Eliminate safeguards against patent abuse**
- **Expand pharmaceutical monopolies through data exclusivity**

See back for more on how the U.S. proposal will hurt access to medicines in Peru.

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Public Citizen's Global Access to Medicines Program

Website:
www.citizen.org/access

Email:
medsaccess@citizen.org

Twitter:
@PCMedsAccess

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Specifically, the U.S. proposal would:

Greatly expand patent scope and promote "ever-greening"

New uses and minor variations of already known medicines would be patentable even if they do not enhance therapeutic value. In some cases, pharmaceutical companies could expand their monopolies by obtaining patent protection on existing medicines for an additional period of 20 years. In 2001, the Andean Tribunal of Justice ruled that such second-use patents conflicted with Andean Community law and ordered INDECOPI, the Peruvian patent office, to revoke Pfizer's second-use patent on Viagra, a treatment against male impotence.

Require patent protection for methods of treating patients

For moral and ethical reasons, World Trade Organization (WTO) rules do not require patent protection for therapeutic, surgical, or diagnostic methods. The US-Peru FTA expressly recognizes this flexibility. The TPP would impose patent protection for each. This could create more cost burdens for the Peruvian health system. For example, hospitals and medical professionals could be required to pay royalties if they use patented methods for treating, diagnosing, or operating on patients.

Further delay access to affordable generic medicines

Drug companies would be able to request patent term extensions if examination at the patent office or regulatory authority exceeds a certain time period. This measure goes beyond requirements in previous FTAs and would allow pharmaceutical companies to extend their patents beyond the WTO standard of 20 years.

Risk facilitating patent abuse

The Dirección General de Medicamentos, Insumos y Drogas (DIGEMID) would be required to condition market approval on patent status (patent linkage--PL). For each generics application, DIGEMID would have to identify whether a patent exists and notify the patent holder. Any existing patent would automatically delay generics approval until the patent is found to be invalid or expires. PL can facilitate patent abuse since the financial benefits of deterring generic market entry may outweigh the risks of penalties. The 2007 US New Trade Policy made PL voluntary for countries negotiating FTAs with the US including Peru.

Eliminate safeguards against patent abuse

The Andean Community Intellectual Property Regime allows third parties such as civil society and health groups, to oppose spurious patents before they are granted. The TPP eliminates this safeguard and allows for more undeserved, low-quality patents that contribute little to innovation but greatly to price.

Expand pharmaceutical monopolies through data exclusivity

The U.S. proposal seeks to implement automatic data exclusivity. Peru would have to provide *at least* five years exclusivity for disclosed and undisclosed information related to new products and *at least* three more years in cases of new uses for old medicines. The Peru-U.S. FTA however, only provides data exclusivity protection for undisclosed test data related to pharmaceutical products containing new chemical entities for five years. The U.S. is expected to table additional data and market exclusivity for biotech medicines, such as cancer and cardiovascular treatments.

For more information, visit: www.citizen.org/tppa

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