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New Peru Trade Text: Improvements for Access to Medicines Threats to Public Health Remain

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The final text of the revised U.S. Peru Trade Promotion Agreement includes substantially new provisions on intellectual property (IP) that will have important implications for access to affordable medicines. The text was released on June 25, 2007.

The original Peru text would have greatly obstructed people's access to affordable medicines in the interests of transnational drug companies, mirroring many other recent agreements. Compared with these earlier agreements, the new Peru provisions represent a decisive step away from the policy of leveraging trade deals to obstruct access to medicines. Vigorous efforts by the new leadership of the House Ways and Means Committee have reigned in the ambitions of the pharmaceutical industry, and added important flexibilities.

The laws Peru adopts to implement the new flexibilities, and how forcefully Peru pursues their implementation will determine whether people do in fact get access to affordable life-saving medicines as soon as possible. Before considering the Agreement, Congress should reverse the course of past trade policy and call for implementing language and practices in Peru on IP that benefit health. They should also insist that knowledgeable health advocates in Peru play an ongoing role in implementation. House Trade Subcommittee Chair Sander Levin has stated publicly that the text should be interpreted to benefit people's access, and we expect he will continue to be a champion. If the Agreement is adopted, Congress should remain vigilant on these issues.

The Agreement's remaining "TRIPS-Plus" rules still exceed the monopoly protections for drug companies already implemented in the WTO's TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights). These will put patients at greater risk than no agreement at all. For example, data exclusivity rules will allow drug companies to market new drugs in Peru at high prices and without competition for up to five years, even if there is no patent in effect.

But the new rules are a victory for advocates and policymakers worldwide, who are supporting the use of compulsory licenses by Thailand and Brazil, and achieving reconsideration of access provisions in the Korea-U.S. Free Trade Agreement. New agreements, starting afresh, must truly promote health, and assure that the benefits of trade are widely shared.

There were no changes in myriad other provisions likely to adversely affect public health, ranging from eliminating tariffs on tobacco products to undermining public health regulations and services. CPATH and colleagues detailed these shortcomings from **Public Health Objectives for Global Trade**, and proposed alternatives, online at: <http://www.cpath.org/id29.html>.

A detailed analysis of the provisions related to access to medicines follows in 3 areas: data exclusivity; linkage; and patent extensions.

CPATH ♦ Ellen R. Shaffer and Joe Brenner, Directors ♦ 98 Seal Rock Drive, San Francisco, CA 94121 USA
phone: 415-933-6204 ♦ fax: 415-831-4091 email: cpath@cpath.org ♦ www.cpath.org

Detailed analysis

Data Exclusivity and Barriers to Compulsory Licenses

The revised text preserves the obligation to provide 5 years of data exclusivity (16.10.2). Data exclusivity provides monopoly protections separate from those provided by patents by preventing drug regulatory authorities from referring to the originator company's clinical trial data that establish a drug's safety and efficacy when registering a generic version. Thus, in order to market the drug during the data exclusivity period, the generic company would need to repeat the clinical trials, which is unethical and expensive. In cases where a patent may not exist for a variety of reasons, or where the patent has expired, the resulting period of monopoly protection allows pharmaceutical companies to delay generic competition and charge high prices. The revised provisions are still TRIPS-Plus, as TRIPS provides a more limited right (it protects some data against "unfair commercial use") and does not mandate any monopoly period.

But the agreement also limits the conditions and terms of data exclusivity in ways that can benefit access, when compared with the terms included in previous FTAs.

The new Agreement limits the application of data exclusivity to "new chemical entities," (16.10.2(a)), meaning it can only be applied to truly innovative drugs, and not to those that simply entail minor modifications to already known substances.

It protects only "undisclosed data" that is the result of "considerable effort." Other versions have allowed originator companies to hold up access even to "information" already in the public domain and that required little investment in order to block approval for generics.

The data exclusivity period is limited to 5 years, not "at least" 5 years. If Peru grants marketing approval to originator companies within 6 months of filing, based on prior approval in the U.S., the data exclusivity period begins with the date of approval in the U.S. (16.10.2.(c)).

A central concern has been whether data exclusivity rules can also block generic production when a government has granted a compulsory license on a patented drug, because the compulsory license on a patent only covers the patent right. Informally, the U.S. Trade Representative (USTR) has agreed in the past that countries have the right to override data exclusivity protections, including in cases where a compulsory license was issued. The final text is far clearer on this point than earlier agreements, though it does not remove all ambiguity decisively.

Article 16.10.2(e) specifically permits countries to protect public health in accordance with the Doha Declaration, adopted as part of TRIPS in 2001, and implies that Doha rights can justify overriding a data exclusivity claim. The Doha Declaration explicitly recognizes that: "Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."

In addition, Article 16.13 of the Peru agreement specifically affirms the commitment to the Doha Declaration and includes some of the Declaration's language, which had been relegated in the past to unenforceable side letters, including the following:

Understandings Regarding Certain Public Health Measures

1. The Parties affirm their commitment to the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2).

2. The Parties have reached the following understandings regarding this Chapter.

(a) The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency. Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all.

16.13.2 improves on the old side letter language, which restricted countries to taking only "**necessary**" measures to protect public health, a limitation not included in the actual Doha Declaration, or this new text.

In June, 2007, Rep. Levin circulated a letter to Congress asserting that the new agreement should be understood to include "an explicit exception to the data exclusivity rules...for measures to protect public health, including the right of each WTO Member to grant compulsory licenses" as stated in the WTO Doha Declaration. The U.S. Trade Representative has failed to uphold legal Doha flexibilities in the past. Before the agreement is considered, and certainly if it is adopted, Congress and advocates must insist on an interpretation that data exclusivity rules cannot block any of the TRIPS flexibilities, including compulsory licenses. Such a crystal clear statement should be included in future agreements.

Patent extensions curbed

The revised text eliminates mandatory extensions for pharmaceutical patents due to delays in granting a patent or regulatory approval (16.9.6(c)). Because of the low patent review capacity in many developing countries, there is a significant and growing backlog of patent applications. Mandatory delays therefore threaten to impose very prolonged periods of patent monopolies.

Linkage eliminated

The revised text eliminates the requirement for "linkage" – a prohibition on the drug regulatory agencies granting regulatory approval without first verifying whether a patent is claimed. As noted by Essential Action and others, "Linkage provisions turn drug regulatory agencies into patent enforcement agencies, even though such a duty is outside of their expertise and purpose. In the United States, which includes significant safeguards (the elements of 16.10.4, plus a large market and robust generic industry), linkage has been subjected to considerable abuse, as recognized repeatedly by the Federal Trade Commission. One unfortunate requirement is that alternative expedited patent enforcement mechanisms be provided before a product is placed on the market." It should be noted that these mechanisms will not be allowed to prevent the regulatory agency's marketing approval process, but must simply be available before the product is actually marketed.

In implementing the agreement, the expedited process should include an opportunity for generic firms to challenge the validity of the underlying patents the brand-name firm is seeking to enforce. The provisions in 16.10.4 could be adopted by countries that have previously entered into TRIPS-Plus agreements with the United States.

The new agreement also allows a new right to challenge a patent, and allows a country to provide incentives to challenge patents (16.10.4.(d)).

Conclusion

The change in course on access to medicines will be truly significant if it is a first step towards a new trade policy that genuinely promotes and protects the public's health.