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Special 301 and Ecuador's TRIPS-Compliant Protocol on Access to Medicines and Compulsory Licensing

– Background –

Washington, D.C., March 3, 2010 – Today, the Office of the United States Trade Representative (USTR) opens public hearings on its annual Special 301 Report to Congress, which lists countries for perceived shortcomings in intellectual property protections. Public health groups have long criticized USTR's 301 process as heavily influenced by the priorities of the big drug companies; pressuring countries to adopt measures not required by global trade rules. These same measures would hamper public access to medicines.

In October, Ecuador's President Rafael Correa declared access to priority medicines affecting the health of the Ecuadorean people to be a matter of public interest. Under Andean Community law, Correa's Decree 118 opens the door to competition of generic medicines with patented brand-name drugs, through use of an internationally recognized legal mechanism called compulsory licensing. The policy could expand access to lifesaving medicines.

Ecuador's compulsory licensing protocol complies fully with the World Trade Organization's TRIPS Agreement on intellectual property. Indeed, Decree 118 borrows provisions directly from the TRIPS Agreement, in some cases employing the TRIPS language word-for-word. Ecuador's patent-office, IEPI, recently issued formal guidance for license applicants in its "Instructivo," further specifying TRIPS-compliant procedures and terms for any licenses considered. Decree 118 and the Instructivo require payments of royalties to pharmaceutical patent holders, procedures for license review and termination, non-exclusivity, and primary supply of the domestic market, among other TRIPS terms. Further analysis is available from Public Citizen.

There would be no defensible rationale for USTR citing Ecuador's TRIPS-compliant compulsory licensing protocol in its 2010 Special 301 Report. Rather, citing the protocol would represent an inappropriate effort by the United States to influence another WTO Member's use of rights preserved by the TRIPS Agreement, with potentially serious consequences for public health.

Globally, competition has consistently proven the most effective method to reduce medicine prices, and ensure prices continue to fall over time. By issuing a compulsory license, a government can authorize generic competition with patented products. Compulsory licenses do not "eliminate" or "override" patents. Instead, they authorize the use of patented technology under enumerated conditions. Countries' right to issue compulsory licenses "on grounds of their choosing" is enshrined in the WTO's unanimous Doha Declaration on the TRIPS and Public Health (2001). Ecuador has yet to issue a compulsory license.

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