



February 12, 2014

USTR's proposal for the Intellectual Property Chapter of the Trans-Pacific Partnership (TPP) will endanger access to medicines for all

Over the last three years, the undersigned groupsⁱ, public health and development expertsⁱⁱ, the Vaticanⁱⁱⁱ, Members of Congress^{iv}, and United States trading partners^v in the Trans-Pacific Partnership Agreement (TPP) negotiations have repeatedly expressed concerns about the public health and global access to medicines implications of the United States Trade Representative (USTR) efforts to augment pharmaceutical monopoly power by creating excessive and additional intellectual property (IP) norms in the TPP.

In response, in November 2013, during the Salt Lake City round of TPP negotiations, United States trade negotiators proposed a “differential treatment approach” to the TPP IP chapter claiming to be extending some of the public health flexibilities included in the 2007 New Trade Policy (May 10 Agreement) to the developing countries currently negotiating the TPP.^{vi}

We are deeply concerned about the public health implications that these measures will have for millions of patients in need of access to affordable medicines around the whole Asia-Pacific region, and about the mischaracterization of this proposal as being coherent with the May 10 Agreement. This “new” approach not only preserves the life-threatening and access-restricting proposals that USTR has been pushing since 2011, forcing all TPP countries to go far beyond internationally agreed World Trade Organization obligations contained in the Trade-Related aspects of Intellectual Property Agreement (TRIPS), but also fails to provide adequate recognition of the urgent access to medicines needs of patients living in developing countries.

Recognizing the detrimental impact of excessive IP protections for developing countries, the May 10 Agreement took a necessary, though still insufficient step in the right direction. The deal provided developing countries negotiating trade agreements with the United States at the time—Peru, Colombia and Panama—flexibilities for the implementation of the most burdensome IP provisions on the table during those negotiations (patent linkage, patent term extensions, and data exclusivity). We are concerned that even the principles of the May 10 Agreement—to avoid the harmful effects of excessive IP protections in less wealthy countries where many people still live in poverty—are not being maintained in the TPP negotiations.

Specifically, we are concerned that the USTR proposal will impose undue burdens on public health in the following ways:

- **USTR's proposal seeks to impose unprecedented and excessive "TRIPS-plus" IP protections for both developed and developing countries.**

The USTR proposal seeks to limit the flexibilities granted under the TRIPS Agreement aimed at protecting public health, and oblige countries to implement new and harsher measures that will endanger access to medicines. Such measures favor the expansion of drug monopolies at the expense of patients' health.

- **The USTR proposal fails to preserve even the modest pro-access steps achieved under the May 10 Agreement.**

The TPP imposes new and harsher measures for health that were never part of the U.S. trade agreements with Peru, Colombia and Panama and therefore were not considered in the May 10 Agreement. Yet, all TPP countries are expected to adopt these new provisions, which include: lower patentability standards that will expand the scope of what can be patented, thus facilitating patent "evergreening" and prolonging access barriers for existing medicines; patents for methods of treating patients such as surgical, diagnostic, and therapeutic medical procedures that will increase healthcare costs and limit availability of medical best-practices, knowledge and care; and a special, extra-long additional period of data exclusivity for biologics that will block access to more affordable biotech medicines that are urgently needed to treat diseases such as cancer and hepatitis.

- **The USTR's differential treatment proposal is not only inadequate in scope – failing to fully incorporate the May 10 Agreement – it is unacceptably limited in scale.**

Under USTR's proposal, only a few of the less wealthy countries will be eligible for differential treatment, and they would *still* be forced to adopt access-restrictive IP protections in the long-term. USTR's differential treatment proposal simply consists of the limited application of some of the harmful provisions of the IP chapter (patent linkage, patent term extensions, and certain types of data exclusivity) for certain developing countries. Yet, the terms of these provisions may still be more restrictive than those afforded to developing countries under the May 10 Agreement. Further, these different standards would only be available until those countries cross a certain income threshold. And they may not be available for other developing countries that may accede to the TPP in the future. By contrast, the terms offered to Peru, Colombia and Panama under the May 10 Agreement were permanent.

We stress the importance of ensuring the negotiations take into account the health needs and economic disparities of ALL patients living in TPP countries, and urge USTR to halt its efforts to limit countries' freedom and flexibilities under accepted international norms to implement IP standards that are most appropriate for their public health needs.

Otherwise, the proposed "high-standard, 21st century" trade deal will prove to be a low standard for public health and jeopardize many, if not millions, of lives.

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- ⁱ [Médecins Sans Frontières \(MSF\)/ Doctors Without Borders, “Governments in Trans-Pacific trade deal urged to reject political trade-offs harmful to access to medicines,”](#) October 2013; [Oxfam International, “US trade policy putting public health at risk,”](#) March 2013; [Public Citizen, “Leaked Documents Reveal Obama Administration Push for Internet Freedom Limits, Terms That Raise Drug Prices in Closed-Door Trade Talks,”](#) November 2013; [HealthGAP, “US’s Proposed TPP Transition Period for Middle-Income Parties is Fools Gold,”](#) November 2013; [“Physicians and Scientists-in-Training Push for Access in TPP Negotiations,”](#) November 2013; [Knowledge Ecology International, “KEI analysis of Wikileaks lead of TPP IPR text, from August 30, 2013,”](#) November 2013; [Statement of the Latin America & Caribbean \(LAC\)-Global Alliance for Access to Medicines on the Trans-Pacific Partnership Agreement \(TPP\) & Access to Affordable Medicines,](#) July 2013.
- ⁱⁱ [“UNITAID Concerned that TPP Negotiations Undermine Public Health Goals,”](#) November 2013; [International AIDS Society Statement from Françoise Barré-Sinoussi and Chris Beyrer on the Trans-Pacific Partnership Agreement and Access to medicines \(TPP\),](#) July 2013; [Knowledge Ecology International, “Joe Stiglitz writes open letter to TPP negotiators,”](#) December 2013.
- ⁱⁱⁱ [Knowledge Ecology International, “Vatican criticizes Trans Pacific Partnership: Holy See statement to 9th WTO Ministerial Conference in Bali,”](#) December 2013.
- ^{iv} [Levin Statement on Trans-Pacific Partnership Negotiations,](#) December 2013; [Representative McDermott, “Worlds Apart: Making Sure Trade Policies Improve Global Health,”](#) Roll Call, 31 May 2013; [Representative Waxman sends letter to USTR expressing concerns for access to medicines,](#) December 2013; [Six Members of Congress Write to President Obama on TPP and Access to Health Care,](#) December 2013; [Five Ranking Members of House of Representative send letter to USTR expressing concerns for access to medicines in developing countries,](#) January 2014.
- ^v [Inside U.S. Trade, “Leaked TPP IP Chapter Reveals Details of Conflicting Drug Proposals,”](#) 15 November 2013.
- ^{vi} [United States Trade Representative, “Stakeholder Input Sharpens, Focuses U.S. Work on Pharmaceutical Intellectual Property Rights in the Trans-Pacific Partnership,”](#) November 2013.