

September 9, 2010

Ambassador Ron Kirk
United States Trade Representative
600 17th Street NW
Washington, D.C. 20508

Dear Ambassador Kirk,

We, the undersigned civil society organizations, write to you regarding intellectual property provisions in the proposed Trans Pacific Partnership agreement (TPP). We are concerned that intellectual property measures that may be included in an eventual agreement could undermine access to medicines, and contravene candidate Obama's promised "support [for] the rights of sovereign nations to access quality-assured, low cost generic medication to meet their pressing health needs under the WTO's Declaration on Trade Related Aspects of Intellectual Property Rights (TRIPS)."

Nearly two billion people still lack regular access to medicines in developing countries. Although several important factors contribute to this, one critical problem is the high price of monopolized medicines. Intellectual property provisions that go beyond the standard required by the WTO's TRIPS Agreement ("TRIPS-plus" measures) restrict generic competition, leading to medicine prices that are unaffordable for most people, and healthcare costs that restrict public programs' ability to provide treatment.

The previous Administration negotiated and signed a series of trade agreements imposing TRIPS-plus measures on developing countries, and restricting the use of TRIPS flexibilities. However, the US-Peru Trade Promotion Agreement, the most recent U.S. trade agreement to be ratified and implemented, benefited from an historic agreement between the U.S. Congress and the previous administration. This May 10th, 2007 agreement achieved an unprecedented reversal in the decade-long trend of increasingly severe intellectual property provisions. Intellectual property provisions in the Peru agreement make patent term extensions and patent linkage voluntary instead of mandatory, and place limits on the term and scope of data exclusivity.

Although the May 10th agreement fell short of adequately addressing access to medicines concerns – its provisions, data exclusivity in particular, still impose new costs on public health – it represented an important progression in U.S. policy. The TPP should build on this progress.

We believe the TPP should limit the intellectual property protections required by various trade agreements in the region to levels no higher than those set by the TRIPS Agreement.

Under no circumstances should the TPP undermine the May 10th agreement by insisting on stricter intellectual property measures than those included in the US-Peru FTA. Under no circumstances should the TPP require accession or adherence to the terms of the proposed Anti-Counterfeiting Trade Agreement (ACTA), which could threaten access to medicines by introducing new rules on damages and injunctions, limiting the free transit of generics and imposing chilling effects on the generics trade. And under no circumstances should the

agreement impose procedural or substantive restrictions on the ability of government agencies, including those at the state level, to regulate drug prices through reimbursement policies.

Instead, to improve on the Bush administration's record, the United States should seek to end the harmful impact of trade agreements on access to medicines. The United States should begin by eliminating data exclusivity requirements, which, in addition to compromising access to medicines, are inconsistent with ethical standards regarding the duplication of tests on humans or vertebrate animals.

The TPP should facilitate, rather than impede, the United States and its trading partners honoring their commitments to access and innovation. The TPP should preserve countries' options to "explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products," in accordance with World Health Assembly Resolution 61.21. And the TPP must respect the WTO's 2001 Doha Declaration on the TRIPS Agreement and Public Health, specifically, that "the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

We look forward to your response. Please direct replies to Peter Maybarduk at Public Citizen, 1600 20th Street NW, Washington, D.C. 20009, pmaybarduk@citizen.org, (202) 588-1000.

Sincerely,

Public Citizen
Center for Policy Analysis on Trade and Health (CPATH)
Center for Reflection, Education & Action (CREA)
Community HIV/AIDS Mobilization Project (CHAMP)
Forum on Democracy and Trade
Harvard Global Health & AIDS Coalition
HealthGAP (Global Access Project)
Initiative for Medicines, Access & Knowledge (I-MAK)
Knowledge Ecology International (KEI)
Maryknoll Office for Global Concerns

Medecins Sans Frontieres - USA (Doctors without Borders)
Missionary Oblates
National Legislative Association on Prescription Drug Prices (NLARx)
NETWORK: A National Catholic Social Justice Lobby
Northwest Coalition for Responsible Investment
Oregon Fair Trade Campaign
Oxfam America
School Sisters of Notre Dame Cooperative Investment Fund
Sciencecorps
United Church of Christ Justice and Witness Ministries