

February 15, 2011

Hon. Craig Emerson, Trade Minister  
Department of Foreign Affairs and Trade of Australia

H.R.H. Prince Mohamed Bolkiah, Minister  
Ministry of Foreign Affairs and Trade of Brunei Darussalam

Hon. Alfredo Moreno Charme, Minister  
Ministry of Foreign Affairs of Chile

YAB Datuk Seri Mustapa Mohamed, Minister  
Ministry of International Trade and Industry, Malaysia

Hon. Tim Groser, Trade Minister  
Ministry of Foreign Affairs and Trade of New Zealand

Hon. Eduardo Ferreyros Koppers, Minister  
Ministry of Foreign Trade and Tourism of Peru

Hon. Lim Hng Kiang, Minister  
Ministry of Trade and Industry of Singapore

Amb. Ronald Kirk, Trade Representative  
Office of the United States Trade Representative

Hon. Vu Huy Hoang, Minister  
Ministry of Industry and Trade, Vietnam

Re: Safeguarding Access to Medicines in the Trans-Pacific Partnership Agreement

Dear Trade Ministers,

We, the undersigned civil society organizations, write to you regarding intellectual property provisions in the proposed Trans-Pacific Partnership Agreement (TPPA). We are concerned that intellectual property measures that may be included in an eventual agreement could undermine patients' access to vital medicines, and contravene promises of a new trade model and "21st century" agreement.

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 World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property (WTO's TRIPS) – so-called "TRIPS-plus" measures – restrict generic competition, leading to

medicine prices that are unaffordable for most people, and healthcare costs that can restrict health programs' abilities to provide treatment or other services, in both developing and wealthier countries.

The parties should seek to end the harmful impact of trade agreements on access to medicines. In the past, the United States (among other countries) has negotiated trade agreements imposing TRIPS-plus measures on trading partners, and limiting flexibilities that could otherwise help promote cost-lowering competition.

Therefore, the best result for many parties to the Trans-Pacific Partnership Agreement may be no intellectual property or pharmaceuticals provisions at all.

Nevertheless, we urge countries that are considering intellectual property chapters in the TPPA to table alternatives to the TRIPS-plus model, including forward-looking proposals that would:

- Establish TRIPS as the maximum standard of substantive protection required by the TPPA and preexisting trade agreements in the region, and
- Assist the effective implementation of TRIPS flexibilities.

We are available to discuss these proposals and some suggested components in detail.

The U.S.-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 10<sup>th</sup>, 2007 agreement achieved an unprecedented reversal in the decade-long trend of increasingly severe intellectual property provisions. Intellectual property provisions in the U.S.-Peru agreement make patent term extensions and patent linkage voluntary instead of mandatory, and place limits on the term and scope of data exclusivity.

The May 10<sup>th</sup> agreement fell short of adequately addressing access to medicines concerns. Its provisions, including data exclusivity, still imposed new costs on public health. Nevertheless, it represented an important progression in U.S. policy. The other TPPA parties should insist that any intellectual property text tabled by the United States build on this progress, beginning by eliminating data exclusivity requirements. Data exclusivity requirements compromise access to medicines and are inconsistent with ethical standards regarding the duplication of tests on humans or vertebrate animals.

Under no circumstances should the TPPA 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 TPPA require accession or adherence to the terms of the controversial proposed Anti-Counterfeiting Trade Agreement (ACTA). And under no circumstances should the TPPA impose procedural or substantive restrictions on the ability of government agencies, including those at the state level, to regulate drug prices through reimbursement policies.

New Zealand's recent TPPA proposal states the parties "should be cautious about moving beyond TRIPS standards under [the] TPP," noting that "there is a tendency towards

overprotection of IP in all our societies, particularly in the areas of copyright and patents.” New Zealand proposes an alternative “TRIPS-aligned” structure, focusing on operational coherence and enforcement, and capacity-building in developing countries. We applaud New Zealand for introducing this alternate vision.

New Zealand’s proposal is a better starting point for any regional IP negotiation than the U.S.-sponsored TRIPS-plus status quo. There are still dangers in each of New Zealand’s proposed focus areas, including considerably increasing the bias of IP enforcement policy toward rights holders.<sup>1</sup> This reveals the risks inherent in negotiating any intellectual property or pharmaceuticals provisions in the TPPA. But New Zealand’s paper also reflects growing awareness of the dangers of TRIPS-plus measures and rigid exclusive rights in many countries.

A 21st century agreement must not accept harmful 20th century terms. Instead, the TPPA should look forward to new, open and flexible policy models. The TPPA should facilitate, rather than impede, the parties honoring their commitments to access and innovation. The TPPA 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.

Finally, the TPPA must respect the WTO’s 2001 Doha Declaration on the TRIPS Agreement and Public Health – not only in principle, but in practice – including specifically Doha’s guarantee 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.”

Broad public consultation, input and review of proposed agreement terms will be essential to safeguarding the sensitive public health interests at stake. We urge the TPPA parties to agree in Chile to release the draft texts and associated country papers after each negotiating round.

We look forward to discussing these issues further. Please direct inquiries to Peter Maybarduk at Public Citizen, 1600 20<sup>th</sup> Street NW, Washington, D.C. 20009, USA, [pmaybarduk@citizen.org](mailto:pmaybarduk@citizen.org), tel. +1 (202) 588-1000.

Sincerely,

Australian Fair Trade and Investment Network (AFTINET)  
Asia Pacific Network of PLHIV (APN+)  
Continental Social Alliance (ASC) Chile  
Forum on Democracy on Trade  
Foundation for Integrative AIDS Research (FIAR)

---

<sup>1</sup> For further analysis of New Zealand’s proposal, the TPPA and access to medicines, see the memos by Third World Network, the Network for Globalization with Equity (RedGE), American University’s Program on Information Justice and Intellectual Property (PIJIP), and Public Citizen, each *available at*: <http://citizen.org/access>.

Global Network of People Living with HIV (GNP+)  
Health Action International (HAI) Global  
Health Action International Peru  
Health GAP (Global Access Project)  
Initiative for Access, Medicines and Knowledge (I-MAK)  
International Treatment Preparedness Coalition (ITPC)  
Latin America-Caribbean-Global Alliance for Access to Medicines (Alianza LAC-Global)  
Network: A National Catholic Social Justice Lobby  
People's Health Movement OZ (PHM OZ Australia)  
People's Health Movement Vietnam  
Peruvian Network for Globalization with Equity (RedGE)  
Positive Malaysian Treatment Access & Advocacy Group (MTAAG+)  
Public Citizen  
Public Health Association of Australia (PHAA)  
Universities Allied for Essential Medicines (UAEM)

With global partner signatories:

Africa Europe Faith and Justice Network (AEFJN)  
AYPADCAM Cameroon  
Brazilian Interdisciplinary AIDS Association (ABIA)  
Canadian HIV/AIDS Legal Network  
Centre for Health Policy and Innovation  
Delhi Network of Positive People (DNP+) India  
Economic Governance for Health (Scotland)  
FTA Watch Thailand  
Foundation IFARMA Colombia  
Foundation Mission Health Colombia  
Health Action International Bolivia  
Health Action International Colombia  
Health Action International Ecuador  
Health Action International Europe  
IPLeft (Korea)  
Salud y Fármacos  
Thai AIDS Treatment Action Group  
Working Group on Intellectual Property of the Brazilian Network for the Integration of Peoples (GTPI)