The Trans-Pacific Partnership Agreement: a threat to affordable medicines and public health

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The 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) made it mandatory for World Trade Organization (WTO) member states to allow 20 year patents on all products including medicines. This triggered a global counter-movement challenging monopoly pricing of essential medicines. Public health advocates urge governments to use public health 'flexibilities' available under TRIPS such as compulsory licensing and nationally defined criteria for patentability. There is now a vibrant global debate on alternatives to patents as mechanisms for funding of medical research¹. The 2001 WTO Doha 'Declaration on the TRIPS Agreement and Public Health' was a response to the global mobilisation for public health and justice. The Declaration affirmed that TRIPS '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'².

The United States since 2001 has sought to undermine the letter and spirit of the Declaration on TRIPS and Public Health through 'TRIPS-plus' provisions in bilateral and regional 'free trade' agreements^{3,4}. One such regional initiative is the Trans-Pacific Partnership Agreement (TPPA) being negotiated between Singapore, New Zealand, Chile, Brunei, the United States, Australia, Peru, Vietnam and Malaysia. Other countries such as Japan, South Korea, and India are likely to join the process. The TPPA is not limited to 'trade' but potentially impacts on the capacity of national governments to implement domestic policy in a range of areas including environmental protection, the regulation of tobacco and alcohol, and health more broadly.

A leaked draft of the negotiating position of the United States Trade Representative (USTR) reveal demands for IPR protection that go well beyond the requirements of TRIPS⁵. The USTR is linked closely to business groups such as the Pharmaceutical Research and Manufacturers of America (PhRMA) which represents 'big pharma'. The determined objective of PhRMA and the USTR is to obstruct and delay as far as possible price competition resulting from the entry of cheaper generic brands. It is a depressing irony that monopoly privileges, granted by governments – patents and other forms of 'intellectual property' – which impede competition, are pursued in the name of 'free trade'.

PhRMA has long criticized medicines insurance schemes premised on cost-effectiveness and reference pricing such as the Pharmaceutical Benefits Scheme (PBS) in Australia and PHARMAC in New Zealand. The PhRMA submission to the USTR on the TPPA specifically targets alleged 'market access barriers... inadequate consultative mechanisms and transparency concerns in countries like New Zealand'⁶. But the governments of Australia and New Zealand are unlikely to accept the whole-sale winding-back of the PBS and PHARMAC. The Australian government affirms that it 'has not and will not accept provisions that limit its capacity to put health warnings or plain packaging requirements on tobacco products or its ability to continue the Pharmaceutical Benefits Scheme'⁷. But US pressures may well result in incremental policy adjustments which weaken cost-effectiveness assessments and reference pricing. The largest generics supplier to the PBS, Alphapharm (a subsidiary of the global generics firm Mylan), is 'deeply concerned about the impact that the [TPPA] could have on the generic pharmaceutical industry in Australia, on consumers and on the Government's budget'⁸.

Of particular concern is the potential impact of the TPPA on access to affordable medicines in developing countries. Prices on first generation HIV drugs have come down radically in the past decade through generics competition, notably through the entry of Indian suppliers such as CIPLA. International programs to treat HIV/AIDS depend on access to affordable quality generic drugs. Leaked documents reveal clearly that the USTR is pursuing aggressive TRIPS-Plus measures, categorises by the Médecins Sans Frontières as follows⁹:

- a. *The USTR is seeking to broaden the scope of patentability to facilitate patenting of new forms of old medicines that offer no added therapeutic efficacy. Governments should no longer be able to define key terms such as 'novelty', 'inventive step' and 'industrial applicability' in a way that reflects national priorities. In India this conflict is focused on paragraph 3(d) in the Indian Patent Act which prevents 'evergreening' by accepting patents on known substances only for therapeutically effective modifications.*
- b. *The USTR wants to disallow pre-grant patent opposition and enhance the legal rights of pharmaceutical companies.*

Pre-grant opposition allows third parties, including NGOs, public health groups, and competing firms, to challenge a patent application as unmerited, thus expediting generic competition.

- c. *The USTR is seeking to bring in new forms of IP enforcement, allowing 'custom officials to seize shipments of drugs on mere suspicion of IP infringement and to increase damages for IP infringement'*¹⁰.
- d. *The USTR is seeking to expand data exclusivity.* Data exclusivity prevents, for a certain number of years, access for generics companies to existing clinical trial data. This results in extension of monopoly pricing beyond the patent period since it is uneconomical (and unethical) for clinical trials already undertaken to be replicated. Data exclusivity is not required under TRIPS.
- e. *The USTR is seeking patent term extensions beyond twenty years to compensate for administrative delays in the regulatory process.* This has the effect of delaying generic competition.
- f. The USTR is seeking to make drug regulatory authorities, charged with evaluating the safety, quality, and efficacy of medicines, responsible also for monitoring of IPRs. 'Linking drug registration and patent status can delay generic entry into the market and is an aggressive TRIPS plus measure'¹¹.

The TPPA is the first trade agreement negotiated under the Obama administration. Remarkably, the US position under Obama represents a step back from the 2001 Doha Declaration on TRIPS and Public Health, the 2008 WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and even the policy adopted by the Bush Administration in 2007¹².

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References

1. Stiglitz, JE, Jayadev, A. Medicine for tomorrow: some alternative proposals to promote socially beneficial research and development in pharmaceuticals. *Journal of Generic Medicines*. 2010;7(3): 217-226.
2. Declaration on the TRIPS agreement and public health. WT/MIN(01)/DEC/2 20 November 2001, Available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm. Accessed at 2 November 2011.
3. Sell, SK. TRIPS-Plus free trade agreements and access to medicines. *Liverpool Law Review*. 2007;28(1): 41-75.
4. 't Hoen, EF M. The global politics of pharmaceutical monopoly power: drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health. Diemen: AMB Publishers; 2009. Available at http://www.soros.org/initiatives/health/focus/access/articles_publications/publications/aem_20090312. Accessed at 2 November 2011.
5. Leaked documents and a wealth of information on the TPPA process is available at several websites, including Knowledge Ecology International <http://keionline.org/>, Public Citizen <http://www.citizen.org/Page.aspx?pid=183>, The Trans-Pacific Partnership Digest <http://tppdigest.org/>, and AFTINET <http://aftinet.org.au/cms/>.
6. Faunce T, Townsend R. Potential impact of the TPPA on public health and medicine policies. Submission to the Department of Foreign Affairs and Trade, Available at, <http://www.dfat.gov.au/fta/tpp/index.html>. Accessed at 2 November 2011.
7. Department of Foreign Affairs and Trade. Gillard government trade policy statement: trading our way to more jobs and prosperity. Available at, <http://www.dfat.gov.au/publications/trade/trading-our-way-to-more-jobs-and-prosperity.pdf>. Accessed at 2 November 2011.
8. Alphapharm (Mylan). Submission to the Department of Foreign Affairs and Trade, Available at, <http://www.dfat.gov.au/fta/tpp/index.html>. Accessed at 2 November 2011.
9. Doctors Without Borders/Médecins Sans Frontières (MSF). How the Trans-Pacific Partnership Agreement threatens access to medicines. Available at, <http://www.doctorswithoutborders.org/press/2011/MSF-TPP-Issue-Brief.pdf>. Accessed at 2 November 2011.
10. Doctors Without Borders/Médecins Sans Frontières (MSF). How the Trans-Pacific Partnership Agreement threatens access to medicines. Available at, <http://www.doctorswithoutborders.org/press/2011/MSF-TPP-Issue-Brief.pdf>. Accessed at 2 November 2011: 4.
11. Doctors Without Borders/Médecins Sans Frontières (MSF). How the Trans-Pacific Partnership Agreement threatens access to medicines. Available at, <http://www.doctorswithoutborders.org/press/2011/MSF-TPP-Issue-Brief.pdf>. Accessed at 2 November 2011: 6.
12. Public Citizen. Leaked drug patent, formulary pricing texts at trans-pacific trade talks reveal U.S. pushing extreme pharmaceutical corporation demands that would undermine consumers' access to affordable medicine. Media release 27 October 2011. Available at, <http://www.citizen.org/documents/statement-tpp-leaked-docs-10-22-2011.pdf>. Accessed at 2 November 2011.