

MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN  
**TRADING AWAY HEALTH:  
THE TRANS-PACIFIC PARTNERSHIP  
AGREEMENT (TPP)**

**USA!**

**HANDS  
OFF**



**OUR  
MEDICINE**

**STOP THE TRANS PACIFIC PARTNERSHIP'S  
ATTACK ON GENERIC MEDICINES**

Unless damaging provisions are removed before negotiations are finalized, the TPP agreement is on track to become the most harmful trade pact ever for access to medicines in developing countries.

The TPP trade deal is currently being negotiated between the U.S. and ten other Pacific Rim nations. The negotiations are being conducted in secret, but leaked drafts of the agreement include aggressive intellectual property (IP) rules that would restrict access to affordable, life-saving medicines for millions of people.

Proposed by U.S. negotiators, the IP rules enhance patent and data protections for pharmaceutical companies, dismantle public health safeguards enshrined in international law and obstruct price-lowering generic competition for medicines.

As a medical humanitarian organization working in nearly 70 countries, Doctors Without Borders/Médecins Sans Frontières (MSF) is concerned about the impact these provisions will have on public health in developing countries where MSF works, and beyond.

Governments have a responsibility to ensure that public health interests are not trampled by commercial interests, and must resist pressures to erode hard-fought legal safeguards for public health that represent a lifeline for people in developing countries. **MSF urges the U.S. government to withdraw—and all other TPP negotiating governments to reject—provisions that will harm access to medicines.**

**A DANGEROUS GLOBAL PRECEDENT**

The TPP is likely to become one of the largest trade pacts ever, encompassing 11 countries today, and potentially open to all 21 Asia-Pacific Economic Cooperation (APEC) nations.

Thailand is in the process of joining, and Japan and the Philippines are actively considering it. Additional countries will be allowed to join later – apparently, however, without the right to amend the text.

Billed as a model for future trade agreements across the globe, the TPP could set damaging precedents with serious implications for many developing countries.

**FLAWED PROCESS SET TO CONCLUDE IN 2013**

The negotiations, which began in 2010, are being conducted in secret, without opportunity for public scrutiny, even though the pact will affect at least half a billion people. TPP negotiators now want the agreement finalized by October 2013.

Current TPP Countries and 2012 estimated GDP per capita\*



**The TPP imposes the same standards on all member countries, even though economic development ranges widely.**

\*International Monetary Fund, World Economic Outlook Database, October 2012.



MSF Access Campaign

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## ROBUST GENERIC COMPETITION IS A CATALYST FOR AFFORDABLE MEDICINES...

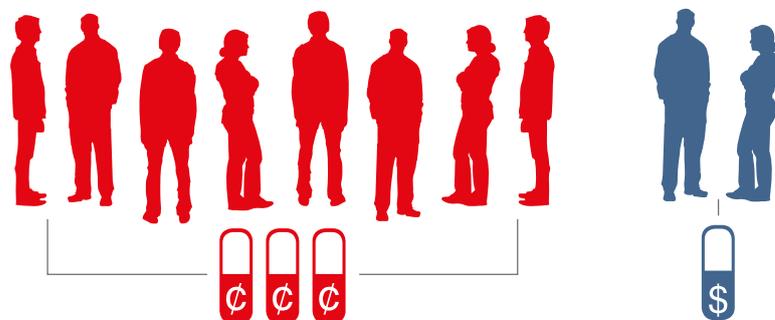
**In the field of health, generic competition saves lives.** As a medical treatment provider, MSF relies on affordable, quality generic medicines to treat many diseases, including tuberculosis, malaria, HIV/AIDS and other infections that afflict the poorest and most vulnerable populations.

Major international treatment initiatives and agencies, including the Global Fund to Fight AIDS, Tuberculosis and Malaria, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) program, UNITAID, and UNICEF, also depend heavily on affordable generic drugs to scale up urgently needed treatment programs. For example, more than 98% of the antiretroviral medicines purchased by PEPFAR to treat HIV/AIDS are low-priced, quality-assured generic medicines.

Robust generic competition was instrumental in bringing down the price of the first generation of antiretroviral medicines by 99% over ten years<sup>1</sup>, a key

### Vital Importance of Affordable Medicines

**80%** of antiretroviral medicines used in developing countries are generics produced in India



Source: Waning B, Diedrichsen E & Moon S. A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries. 2010. Journal of the International AIDS Society, 13:35.

factor that allowed HIV/AIDS treatment to be scaled up to more than eight million people in developing countries today. But many newer medicines are locked up by patent monopolies that protect high prices for manufacturers and keep vitally important medicines out of reach for people in developing countries.

**Governments that pay for treatment programs, either directly or by funding global health treatment initiatives, have both an interest and a responsibility to ensure that new roadblocks are not put in the way of generic competition, or they risk jeopardizing the effectiveness of the very programs they support.**

## ... BUT COMMITMENTS TO PUBLIC HEALTH AND MECHANISMS TO PROMOTE COMPETITION ARE CONTINUALLY ERODED BY COMMERCIAL INTERESTS

The availability of generic medicines in a particular country depends on a complex structure of laws and regulations, including those governing patents and other intellectual property rights. Many of these regulations are influenced by trade and other types of international agreements.

In 1995, the World Trade Organization's TRIPS agreement<sup>2</sup> imposed minimum IP standards across the globe for the first time, including the obligation to grant patent monopolies for pharmaceutical products. Importantly, TRIPS includes legal safeguards that give countries some leeway in overcoming IP barriers when they hinder access to medicines, and flexibility in balancing commercial interests and public health. Subsequently, governments have made multiple commitments<sup>3</sup> reaffirming the importance of protecting public health over commercial interests.

Yet the legal tools and safeguards used to counterbalance commercial interests in favor of public health are continually under attack. Developing countries that try to promote the use of generics are frequently the target of litigation by pharmaceutical firms<sup>4</sup> and are subject to diplomatic pressures, such as the threat of sanctions, by Western governments seeking to protect commercial interests.<sup>5</sup> These same forces seek to impose new and ever more restrictive IP rules, known as TRIPS-plus provisions, on developing countries. **TRIPS-plus provisions serve to extend monopoly protection beyond what is required by international agreements and to create new kinds of monopolies, even after patent-based monopolies have expired or where they never existed.** For pharmaceuticals and other health commodities, stronger IP standards mean extended patent monopolies and delayed generic competition, and that

translates into higher prices for people who need medicines, for longer periods of time.

**The TPP represents the most far-reaching attempt to date to impose aggressive TRIPS-plus IP standards that further tip the balance towards commercial interests and away from public health. In developing countries, where people rarely have health insurance and must pay for medicines out of pocket, high prices keep lifesaving medicines out of reach and are often a matter of life and death.**



(c) Fernando Fujimoto

“U.S. negotiators are sidelining concerns about the impact their demands will have on access to medicines. It’s time for TPP negotiators from all countries to acknowledge the harmful effects of these provisions, and to remove them from the TPP agreement.”

JUDIT RIUS, US MANAGER, MSF ACCESS CAMPAIGN

## THESE SEVEN TRIPS-PLUS PROVISIONS ARE NOT REQUIRED BY INTERNATIONAL LAW AND SHOULD BE REMOVED

PROPOSED PROVISION	IMPACT ON ACCESS TO MEDICINES
<b>Lowering the bar of patentability</b> – require patenting of modifications of old medicines, even in the absence of therapeutic benefits.	<b>Some countries currently prohibit or limit the patenting of newer forms of existing medicines, known as “evergreening,” because it keeps medicine prices high and delays the availability of more affordable generics.</b> This provision is designed to prevent countries from including public health safeguards in their national patent law that prevent evergreening, for example as India has done with Section 3(d) of their patents act.
<b>Patenting of medical methods</b> – require the patenting of surgical, therapeutic and diagnostic methods.	<b>Such measures could increase medical liability and the costs of medical practice, and reduce access to basic medical procedures.</b> Several medical associations have declared patenting of medical procedures unethical, and U.S. law prohibits enforcement of these patents on medical practitioners.
<b>Prohibit pre-grant oppositions</b> – forbid challenges to weak or invalid patents until after they have been granted	Drug companies routinely file many patents on aspects of the same drug to avoid generic competition for as long as possible, but it’s a myth that every patent application filed is valid. Pre-grant oppositions constitute an important form of public oversight that helps reduce over-patenting and evergreening, which can cause unwarranted delays to generic competition. <b>Restricting pre-grant oppositions makes it more expensive and cumbersome to challenge weak or invalid patents.</b>
<b>Data exclusivity</b> – prevent drug safety regulators from using existing clinical data to give market approval to generic or biosimilar drugs.	<b>Data exclusivity grants a distinct monopoly status to medicines, even when patents no longer apply or exist, giving companies a new way to keep prices high for longer and further delay generic competition.</b> In addition, existing generics can be forced off the market when these new backdoor monopolies are created. This is the first time the U.S. has demanded data exclusivity for a newer class of drugs called biologics, which are used to treat cancer and many other conditions. If data exclusivity is imposed, the availability of biosimilars – the generic equivalent of biologic drugs – would be considerably delayed. The UN recommends against data exclusivity for developing countries.
<b>Patent term extensions</b> – require extending 20-year patent monopolies by at least five years to compensate for delays in the regulatory process.	At present, patents on drugs in most countries last for 20 years from the date of filing. There is no more straight-forward way to extend a company’s monopoly over a drug than to extend the life of the drug’s patent beyond 20 years. <b>The extra years added to the patent are extra years in which the patent holder can maintain a monopoly position and continue to charge artificially high prices for the drug, free from generic competition.</b>
<b>Patent linkage</b> – prohibit national drug regulatory authorities from approving generic medicines until patents have expired.	At present a drug’s patent status and its registration status are derived from two separate processes. Linking patent status to the registration of medicines means that the drug regulatory authority is required to withhold marketing approval for a generic version of a patented drug regardless of whether the patent granted is valid or not. <b>Patent linkage not only delays generic competition, but can also undermine the use of compulsory licenses and circumvent normal patent dispute processes in the judicial system.</b> Pharmaceutical companies are responsible for monitoring and defending against potential infringements on their own patents. But patent linkage transfers this burden to governments, making it the responsibility of drug safety regulators to police private patents. WHO has warned developing countries against implementing patent linkage, which is further not required in most European countries.
<b>Require new forms of IP enforcement</b> – grant customs officials new powers to detain shipments, including in-transit shipments, suspected of non-criminal trademark infringements; require mandatory injunctions for alleged IP infringements; raise damages amounts.	<b>Increases the risk of unwarranted interruptions and delays in the flow of legitimate trade in generic medicines and limits the judicial system’s capacity to balance commercial and public health interests in patent disputes.</b> These new forms of IP enforcement are reminiscent of the stalled Anti-Counterfeiting Trade Agreement (ACTA), a multinational treaty that sought to impose stringent IP rules. These provisions strip away the ability of governments to define their own enforcement provisions as allowed by international law.

### MSF IS ALSO CONCERNED ABOUT OTHER PROVISIONS PROPOSED FOR THE TPP, INCLUDING:

- ❖ provisions in the **Pharmaceutical Pricing Chapter** that would restrict the ability of governments to use reimbursement or price control systems to reduce healthcare costs
- ❖ provisions in the **Investment Chapter** that would give pharmaceutical companies the right to sue governments for regulations that reduce their expected profits in a private, supra-national tribunal whose decisions are usually unappealable

## MSF URGES ALL GOVERNMENTS NEGOTIATING THE TPP TO:

### ❖ Remove TRIPS-plus requests:

TPP negotiators should not agree to final text that includes TRIPS-plus provisions, which can severely limit access to medicines in developing countries. Instead, TPP negotiators must insist on language that protects public health safeguards and enables developing countries to effectively balance commercial interests and public health.

### ❖ Increase transparency:

Trade negotiations that affect public health must be conducted with adequate levels of transparency and public scrutiny, including providing access to the negotiating texts.

### ❖ Fulfill previous commitments to

**access to medicines:** TPP negotiators should ensure that the final text is aligned with global health priorities and specifically mentions and honors relevant public health commitments, including the 2001 WTO Doha Declaration on TRIPS and Public Health and the 2008 WHO Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property. In addition, the U.S. should adhere to its own May 10, 2007 New Trade Policy, which includes a commitment to refrain from imposing some of the most damaging TRIPS-plus provisions on developing countries.

“Generic production has enabled steep price reductions for HIV drugs over the past decade. But prices for newer lifesaving medicines—including second-line HIV drugs and treatments for hepatitis, tuberculosis, cancer and many other diseases—are climbing rapidly. If pharmaceutical companies are allowed to create patent thickets and extend monopolies unchecked, generic competition will be further delayed—and access to treatment blocked—for millions in developing countries.”

**DR. MANICA BALASEGARAM,  
EXECUTIVE DIRECTOR,  
MSF ACCESS CAMPAIGN**



(c) Dieter Telemans



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## MORE INFORMATION

Visit [msfaccess.org/tpp](http://msfaccess.org/tpp) for more information on the TPP's impact on access to medicines, including our full MSF Issue Brief on the topic: *“How the U.S.'s Intellectual Property Demands for the Trans-Pacific Partnership Agreement Threaten Access to Medicines.”*

1 MSF Untangling the Web of Antiretroviral Price Reductions, 15th Edition, July 2012. Available from [utw.msfaccess.org](http://utw.msfaccess.org)

2 The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights.

3 For example, 2001 WTO Doha Declaration on TRIPS and Public Health; 2008 WHO Global Strategy and Plan of action on Public Health, Innovation and Intellectual Property; 2011 UN Political Declaration on HIV/AIDS; 2011 UN Political Declaration on Non-Communicable Diseases (NCDs). In addition, the US May 10, 2007 New Trade Policy scaled back harsh US government IP trade demands for developing countries, including patent linkage, patent term extensions and data exclusivity.

4 For example, <http://www.msfaccess.org/novartis-drop-the-case> and <http://www.msfaccess.org/resources/press-releases/1892>

5 For example, <http://www.msfaccess.org/content/submission-us-trade-representative-regarding-2012-special-301-review-process>