Trading Away Health

How the Trans-Pacific Partnership Agreement Threaten Access to Affordable Medicines – a Medical Treatment Provider Perspective

Presented by:
Judit Rius Sanjuan, attorney
U.S. Manager of the MSF Access Campaign
Doctors Without Borders/Médecins Sans Frontières

Why is MSF concerned about the TPP?

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***Doctors Without Borders/Médecins Sans Frontières (MSF)**, founded in 1971, is an international, independent, medical humanitarian organization that delivers emergency aid to people affected by armed conflict, epidemics, natural disasters and exclusion from healthcare in nearly 70 countries.*

***MSF's Access Campaign** works to lower the cost of medicines, vaccines and diagnostics to promote increased access to life-saving treatment and research and development of new medical tools that better meet the needs of patients.*

- **MSF is concerned about the public health implications of some provisions currently under negotiation in the TPP, which seem to be aimed at promoting the use of brand-name products and hindering generic competition**
- **As the TPP aims to have a precedent-setting effect for the whole Asia-Pacific region, MSF is concerned that these restrictive policies will be imposed on many developing countries, including where MSF works**

Vital Importance of Generic Competition

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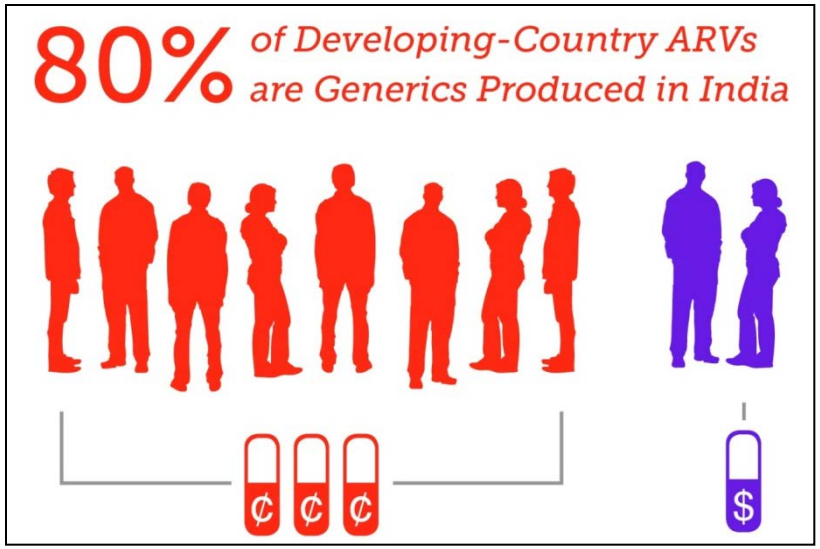
- Historical treatment scale up on HIV/AIDS treatment since 2000 - Today, more than 8 million people in developing countries receive antiretroviral therapy (ART)
- **Treatment scale-up has been possible because of huge price drops due to generic competition**
- Global Fund, UNITAID, Ministries of Health and NGOs rely heavily on **generic drugs as a critical component of sustainable treatment programs:**
  - 98% of PEPFAR's ARV are generic, up from 15% in 2005 - Generics saved PEPFAR $380 million in 2010 alone

MSF's Use of Generic Medicines

- **Most of the AIDS drugs that MSF uses worldwide are generics**
- **MSF routinely also relies on generic drugs to treat TB, malaria, and a wide range of infectious diseases**



Competition = The Price of AIDS Drugs Fell by 99%

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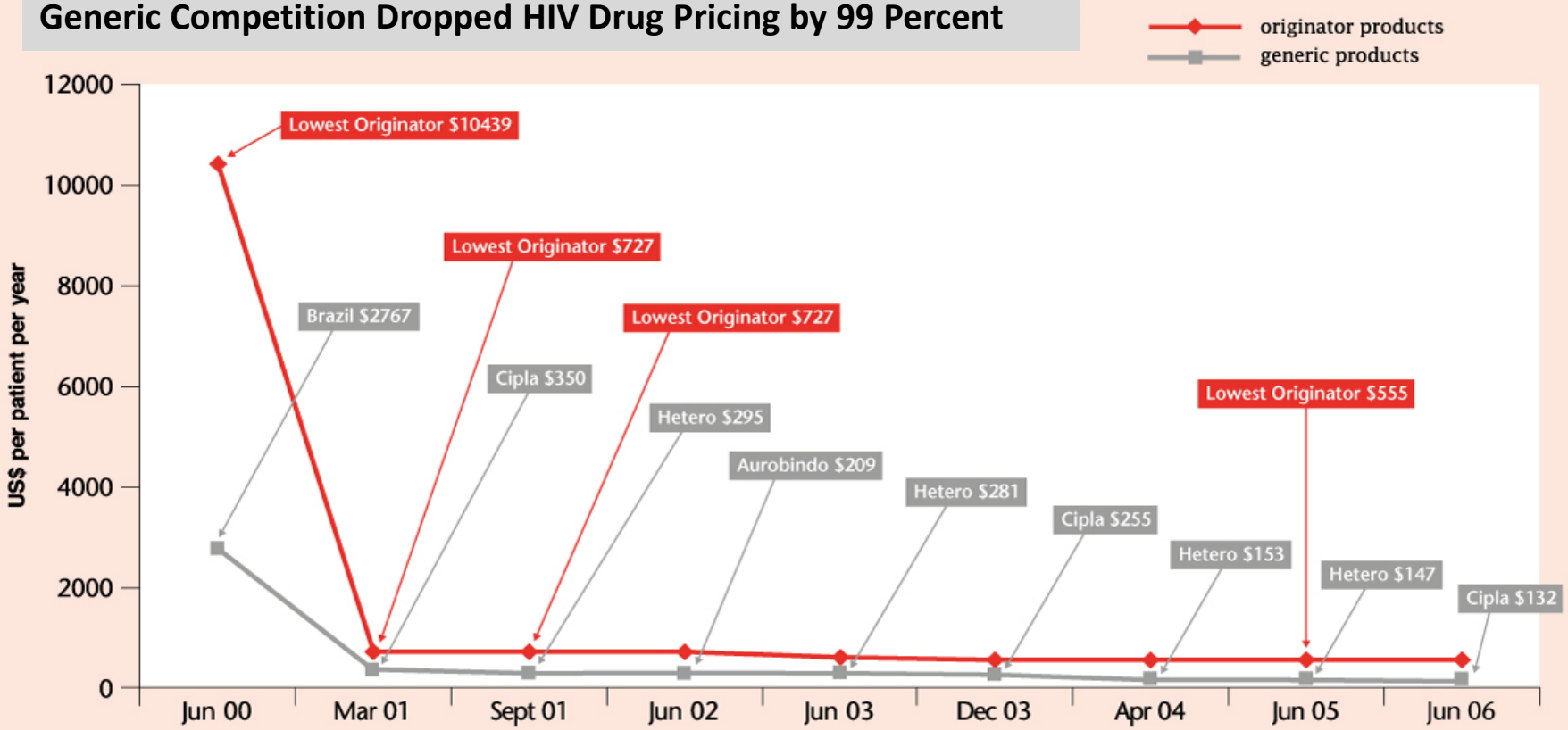
Generic Competition Dropped HIV Drug Pricing by 99 Percent



Source: MSF Untangling the Web of Antiretroviral Price Reductions, 15th Edition, July 2012

Next Generation Drugs Prohibitively Expensive

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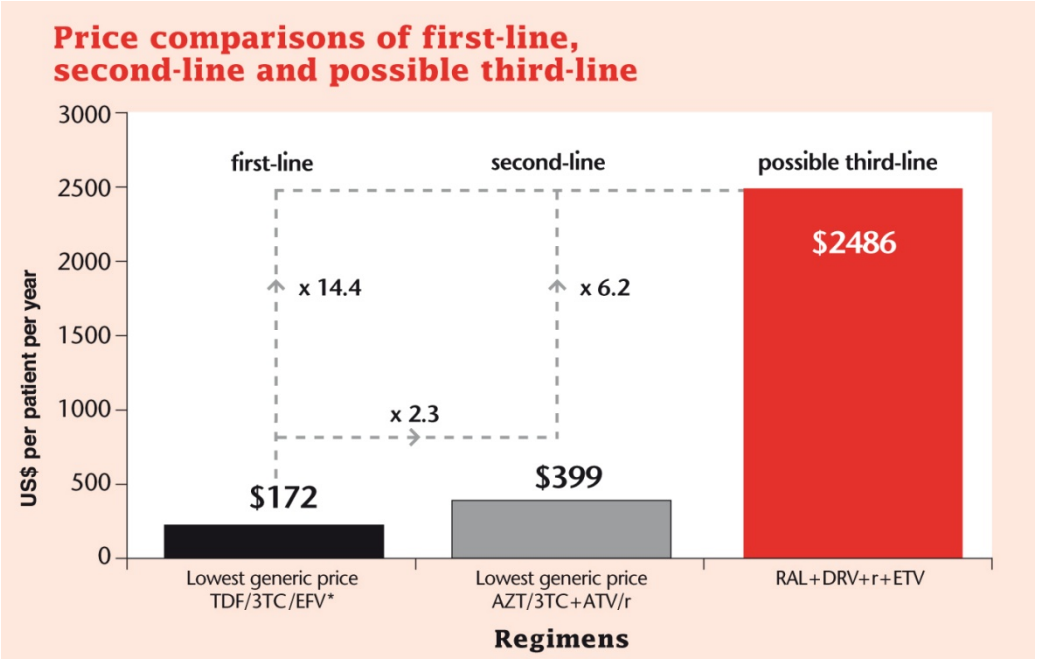
- **Patents and other IP barriers keep medicine prices high and restrict generic competition**
- WTO TRIPS (2005) – **Effects starting to become apparent in developing countries for newer medicines** – e.g. Demand for second-line HIV/AIDS treatments is growing fast: almost half a million people will need these medicines this year
- The most affordable second-line regimen is still **twice as expensive** as the WHO recommended first-line regimen
- The price of a third-line regimen is **more than 14 times higher** than the recommended first-line



Source: MSF Untangling the Web of antiretroviral Price Reductions, 15th Edition, July 2012

Making the situation worse - TPP provisions will make it harder to access medicines

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Leaked text shows that the U.S. is demanding aggressive provisions that would roll back public health safeguards enshrined in international and national laws in favor of offering enhanced patent and other IP protections for pharmaceutical companies, making it harder to gain access to affordable generic drugs.

US demands in TPP are UNPRECEDENTED: the most hard-line proposals we have ever seen in a trade negotiation

The provisions aim to:

- Create new, enhanced and extended patent and other IP provisions that are TRIPS-Plus aimed at allowing multinational pharmaceutical companies to maintain monopolies and charge higher prices for longer and keep price-lowering generic competitors out of the market for longer
- Preclude the use of legal flexibilities to protect public health

Making the situation worse - TPP provisions Affecting Access to Affordable Medicines

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Some of the USTR demands in the TPP negotiation that will negatively affect access to medicines:

- Lower requirements for patentability
- Mandate patenting of diagnostic, therapeutic, and surgical methods
- Prohibit pre-grant patent oppositions
- Mandate data exclusivity and expand protection for biologics
- Extend patent terms
- Mandate patent registration linkage
- Introduce new forms of IP enforcement
- Investment chapter: definition includes IP and contains extra-judicial investor-state dispute resolution provisions
- Transparency/Pharmaceutical chapter: conditions for national drug pricing and reimbursement programs that will limit the capacity to lower prices
- **The USTR proposed "TEAM – Access Window" is a misnomer that actually restricts generic competition**

The **U.S. Government is turning its back on the May 10, 2007 New Trade Policy,** a Congressional agreement to include minimum public health safeguards in trade agreements with developing countries, including making patent term extensions and linkage optional, and limits to data exclusivity

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Lower requirements for patentability

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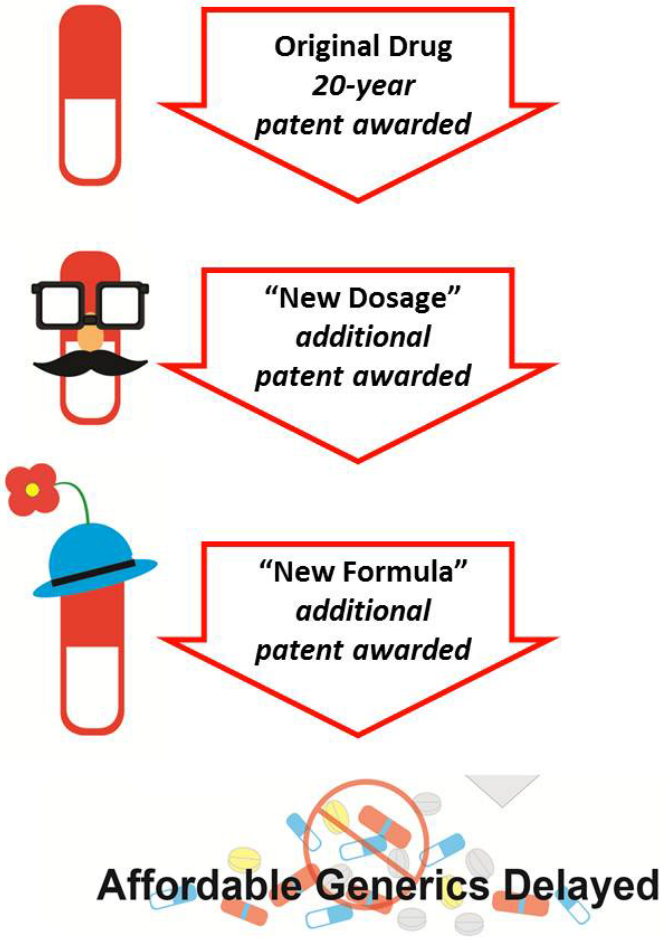
Consequences:

- Makes it easier to <u>patent minor modifications of old medicines and to patent standard industry practices</u>, regardless of whether they offer any increased therapeutic efficacy for patients
- Enables ***<u>evergreening</u>***, the practice whereby pharmaceutical firms <u>extend monopoly protection, potentially indefinitely,</u> by patenting modifications of an existing drug
- **<u>Delays generic production</u> of drugs beyond their original 20-year patents**



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Patentability of medical methods

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The U.S. seeks to require that diagnostic, therapeutic and surgical methods for the treatment of humans or animals be patentable, even though:

- The TRIPS WTO explicitly allows governments to exclude these methods from patent protection
- U.S. law exempts practicing surgeons from patent liability (since 1996 after several lawsuits against doctors)
- World Medical Association has said it is an unethical interference on patient care, it poses risks to the effective practice of medicine and increases the cost of healthcare
- First time that the U.S. has included requirements to patent medical methods in a trade agreement with developing countries

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Relevant for MSF - it can potentially raise doctors' liabilities if they are found to infringe a patent during the practice of a medical diagnostic, treatment or surgical operation.

Prohibition of pre-grant patent oppositions

- **Prohibits challenges to patents before they are granted - weak, invalid or frivolous patents will be granted**
- **Costly and cumbersome litigation** required to oppose patents that have already been granted
- **Deprives patent offices of third party expertise** in evaluating patent applications
- Drugs protected by patents later found invalid will have enjoyed **unwarranted monopoly status and delayed generic production**

MSF Access Campaign experience: Patent oppositions are an essential public health safeguard that can accelerate the entry of generic competition, improve the patent system through public oversight, and help reduce over-patenting.

Lack of innovation to meet developing country needs

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Stringent IP protection and enforcement norms are often justified based on the premise that they are uniquely necessary as a means of encouraging innovation and the development of new medicines.

•However, as the WHO Commission on Intellectual Property, Innovation and Public Health (CIPIH) concluded in 2006 "for diseases affecting millions of poor people in developing countries, **patents are not a relevant factor or effective in stimulating R&D and bringing new products to the market**."
•In fact, stringent IP norms have had little to no effect in spurring innovations needed for developing countries, and in reality have detrimental effects access.
•In contrast, the absence of IP regulations has yielded positive results in innovation to meet developing country needs, for example in allowing the development of better adapted and more appropriate medical technologies, such as fixed-dose combinations and pediatric formulations of HIV medicines.

In April 2012, a landmark report by the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG), concluded that **a different innovation system is needed**, including incentives mechanisms that de-link or separate the costs of research and development from the price of products.

MSF Recommendations

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- **Increase transparency:** Trade agreement negotiations that affect public health must be conducted with adequate levels of transparency and public scrutiny – RELEASE the TPP text

- **Withdraw TRIPS-plus requests** and include provisions that will **promote access to affordable medicines, competition and patient-driven innovation**

- **TPP should be aligned with global health priorities and previous commitments to access to medicines and innovation,** including:
  - 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 Declarations on HIV/AIDS and NCDs

More information

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- **Contact information:**

  Judit Rius Sanjuan, attorney
  U.S. Manager of the MSF Access Campaign
  Doctors Without Borders/Médecins Sans Frontières (MSF)
  Office: +1 212 655 3762
  Email: judit.rius@newyork.msf.org

- **MSF Access Campaign Latest Briefing Note on TPP:**
  http://www.msfaccess.org/content/trading-away-health-how-uss-demands-tpp-threaten-access-medicines

- **More information on the MSF Access Campaign**
  http://www.msfaccess.org/

- **More information on Doctors Without Borders**
  http://www.doctorswithoutborders.org/