



Trading Away Health

How the U.S.'s Intellectual Property Demands for the Trans-Pacific Partnership Agreement Threaten Access to Medicines

Encompassing eleven countries and slated for further expansion across the Asia Pacific region, the **Trans-Pacific Partnership Agreement (TPP)** is a regional trade agreement that will “**set the standard for 21st-century trade agreements going forward.**”¹

The TPP negotiations are being conducted in secret, but leaked drafts² of the U.S. negotiating positions show that the U.S. is demanding aggressive intellectual property (IP) provisions that would **roll back public health safeguards** enshrined in international trade law in favor of offering enhanced patent and data protections to pharmaceutical companies, **making it harder to gain access to affordable generic drugs and hindering needed innovation.**

If the U.S.'s demands are accepted, the TPP agreement will impose new IP rules that could severely restrict access to affordable, life-saving medicines for millions of people. Billed by President Obama as “a model not just for countries in the Pacific region, but for the world generally,”³ the TPP will set a damaging precedent with serious implications for developing countries where MSF works, and beyond.

Affordable Medicines Vital to MSF's Work

Doctors Without Borders/Médecins Sans Frontières (MSF) 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 began providing antiretroviral (ARV) treatment for HIV/AIDS in 2000, and now treats 222,000 people in HIV/AIDS projects in 23 countries.

More than 80% of the AIDS drugs that MSF uses worldwide are generics from India. MSF routinely also relies on generic drugs to treat TB, malaria, and a wide range of infectious diseases.

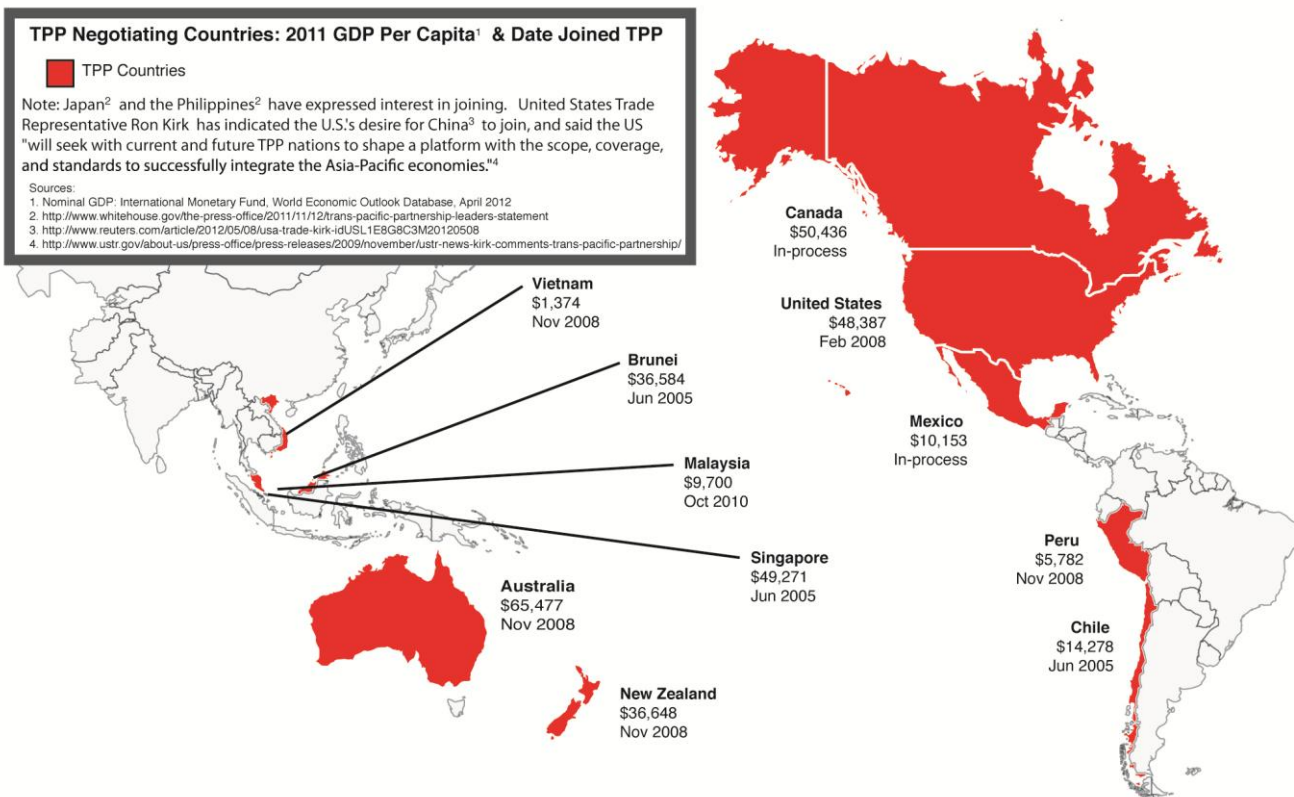


More than 80% of HIV/AIDS drugs purchased to treat patients in developing countries are generics produced in India.

MSF is concerned about the public health implications of the U.S.'s IP demands on the countries currently negotiating the TPP. Furthermore, as the final text of the TPP is likely to become a precedent for future trade agreements and IP negotiations, MSF is concerned that these restrictive IP policies, known as “TRIPS-plus” provisions, will be imposed on additional developing countries, including where MSF works, affecting access to medicines for millions of patients.

TPP Slated to Expand Across Asia Pacific Region

The agreement imposes the same standards on all countries, regardless of economic development



Closed-Door Negotiations with Far-Reaching Impacts

MSF opposes the secrecy under which the TPP negotiations are being conducted, which forces MSF, civil society and other interested stakeholders to rely on “leaked texts” to evaluate the impact of an agreement that will affect more than half a billion people in at least 11 countries, and potentially many more. The closed-door nature of the TPP negotiations has also come under intense criticism from some members of the U.S. Congress (*see Appendix B*), as well as public health advocates and consumer groups,⁴ who have asked the U.S. Administration to increase transparency and allow public scrutiny by making negotiating positions and texts public. As it stands, only the final agreed-upon text will be made publicly available – after it is too late to evaluate the public health impact or modify egregious provisions.

TPP Negotiating Rounds

Next: Round 14: Leesburg, VA, Sep 6-15, 2012

Previous:

Round 13: San Diego, CA, Jul 2-10, 2012

Round 12: Dallas, TX, May 8-18, 2012

Round 11: Melbourne, Mar 2-9, 2012

Round 10: Kuala Lumpur, Dec 5-9, 2011

Round 9: Lima, Oct 22-29, 2011

Round 8: Chicago, Sep 6-15, 2011

Round 7: Ho Chi Minh City, Jun 15-24, 2011

Round 6: Singapore, Mar 24-Apr 1, 2011

Round 5: Santiago, Feb 14-18, 2011

Round 4: Auckland, Dec 6-10, 2010

Round 3: Brunei, Oct 4-9, 2010

Round 2: San Francisco, CA, Jun 14-18, 2010

Round 1: Melbourne, Mar 15-19, 2010

The norms that emerge from these negotiations are expected to serve as a baseline for future trade agreements, potentially impacting a much wider group of countries. Yet unlike in negotiations under the auspices of the World Health Organization (WHO), World Trade Organization (WTO) or World Intellectual Property Organization (WIPO), the TPP process does not allow public scrutiny of the specific provisions being negotiated. Meanwhile, more than 600 corporate representatives on government advisory boards *do* have full access to the U.S. negotiating positions.⁵

Most Egregious U.S. Demands Affecting Access to Medicines

According to leaked drafts of the negotiating texts, the U.S. is demanding aggressive intellectual property provisions—so-called “TRIPS-plus” provisions—that, if accepted, would directly undermine public health safeguards available in international law, making it harder for TPP countries to gain access to price-lowering generic competition.

Some of the specific TRIPS-plus IP provisions that the U.S. is demanding:

- **Make it impossible to challenge the validity of a patent before it is granted**
- **Lower the requirements for patentability, so that minor alterations of existing medicines can be given additional protected monopoly status, even if the alteration offers no therapeutic benefit**
- **Require the patenting of diagnostic, therapeutic and surgical methods**
- **Lengthen patent monopolies for pharmaceutical firms so that they keep generics out and prop up drug prices for longer periods of time**
- **Make it harder for generic manufacturers to obtain regulatory approval for their drugs**
- **Create additional monopolies based on clinical data**
- **Impose new forms of IP enforcement that give customs officials excessive powers to impound legitimate generic medicines**
- **Impose higher prices on national pharmaceutical reimbursement programs**
- **Allow pharmaceutical companies to sue governments and limit governments’ abilities to effectively set prices for medicines and legislate in the interest of public health**

By insisting on the inclusion of these provisions, the U.S. is turning its back on existing commitments to preserve public health safeguards in trade agreements with developing countries, including a bipartisan congressional agreement and numerous multilateral agreements under the auspices of the United Nations, World Trade Organization (WTO) and World Health Organization (WHO).

Furthermore, the U.S.’s hardline IP demands threaten the sustainability of the very global health programs it supports, including U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria, which rely heavily on availability and affordability of generic medicines.

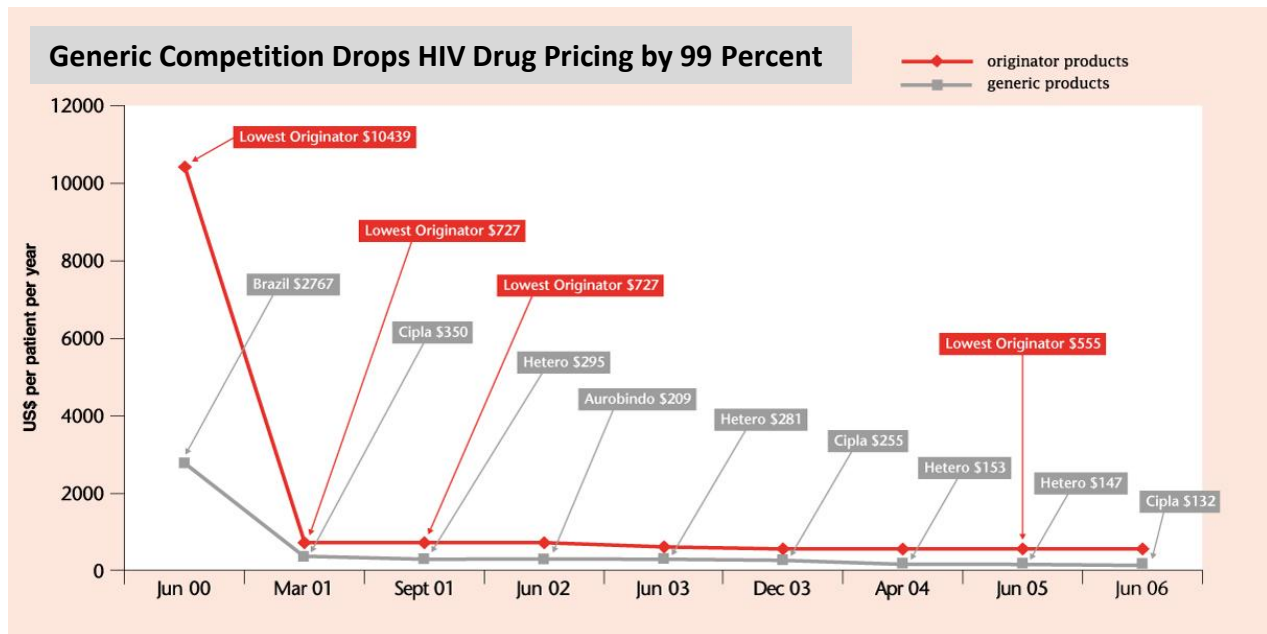
MSF Recommendations

- **Withdraw TRIPS-plus requests:** The U.S. should not seek to impose TRIPS-plus provisions (i.e., broader scope of patentability, limits on patent oppositions, new forms of enforcement, data exclusivity, patent extensions, and patent linkage) on TPP countries. At a minimum, the U.S. government should not walk away from bipartisan public health protections established in the May 10, 2007 New Trade Policy agreement.
- **Increase transparency:** The TPP is being negotiated in secret. Trade agreement negotiations that affect public health must be conducted with adequate levels of transparency and public scrutiny, both with respect to the actual negotiating texts under discussion and the relevant negotiating positions and demands of each country.
- **Recognize previous commitments to access to medicines and innovation:** The U.S. should ensure that the final text of the TPP agreement is aligned with U.S. global health priorities and specifically mentions and honors the commitments made in the 2001 WTO Doha Declaration on TRIPS and Public Health, the 2008 WHO Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property, and the U.S.’s own May 10, 2007 New Trade Policy, a bipartisan agreement to include important global public health safeguards in trade agreements with developing countries.

Generic Competition as a Catalyst for Access to Medicines

In the field of health, generic competition saves lives. Monopolies enforced by patents and other intellectual property regimes keep the price of medicines out of the reach for many patients, especially in the developing world.

The price of HIV treatment has fallen by roughly 99 percent over the last ten years—from over US\$10,000 for one year's treatment in 2000, to less than \$150 per person per year today, thanks to generic production in India, Brazil, and Thailand, where these drugs were not patented. This dramatic price drop has been instrumental in helping scale up HIV/AIDS treatment for more than eight million⁶ people in developing countries.

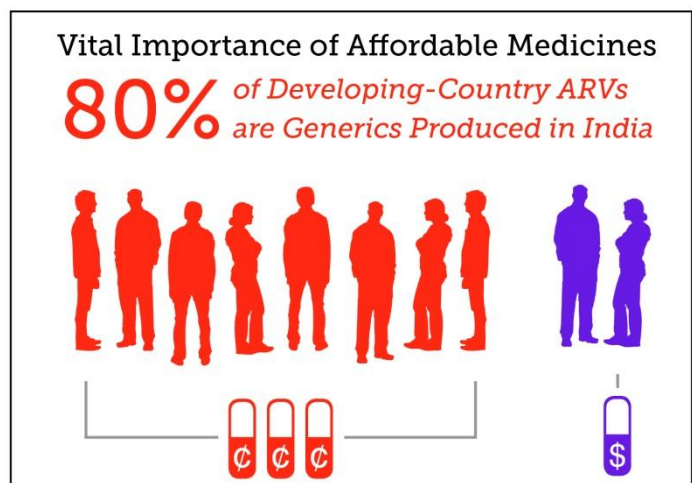


The price for first-line ARVs fell by 99% over ten years.

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

All the major international treatment initiatives for developing countries, including the Global Fund, PEPFAR, UNAIDS, and UNICEF, rely on affordable, quality generic drugs as a critical component of sustainable treatment programs.

By 2008, more than 80% of donor-funded purchases of ARVs for use in developing countries were generics from India, including 91% of those formulated for children.⁷ In 2010 alone, PEPFAR reported saving \$380 million through the purchase of generic versus originator ARVs.⁸



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*, 15:35.

The Role Intellectual Property Plays in Blocking Access to Affordable Medicines

The TRIPS Agreement

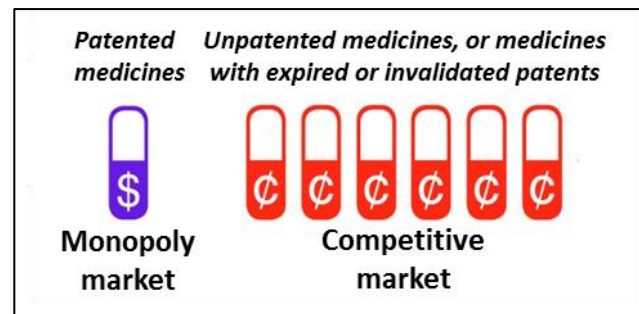
Prior to the creation of the World Trade Organization (WTO) in 1995, countries retained the right to shape their intellectual property laws to meet national needs; as a result, many countries did not grant patents on pharmaceuticals, or made use of flexibilities in IP law to balance commercial and public health interests, ensuring that “the interests of profit” did not impede “delivery of health care.”⁹

When the WTO was formed, the world’s most comprehensive multilateral agreement on IP to date came into force:¹⁰ the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement). The TRIPS Agreement imposes minimum standards for protecting and enforcing IP rights, including a 20-year minimum for patent protections,¹¹ and determines many of the rules that restrict or enable access to medicines. **Developing countries have since struggled to strike a balance between protecting public health and implementing TRIPS-compliant intellectual property laws.**

Patents and IP Hinder Affordability, Accessibility of Medicines

Patents keep the price of medicines high and are a barrier to accessing affordable drugs. In developing countries, where people often pay for drugs out of their own pockets and very seldom have health insurance, the high price of medicines becomes a question of life and death.

When patent barriers are removed, competition between manufacturers enables production of more affordable generic versions of medicines. The impact can be tremendous: **competition helped to reduce the price of first-line HIV/AIDS drugs by 99 percent over the last decade.**



Doha Declaration Affirms TRIPS Flexibilities to Protect Public Health

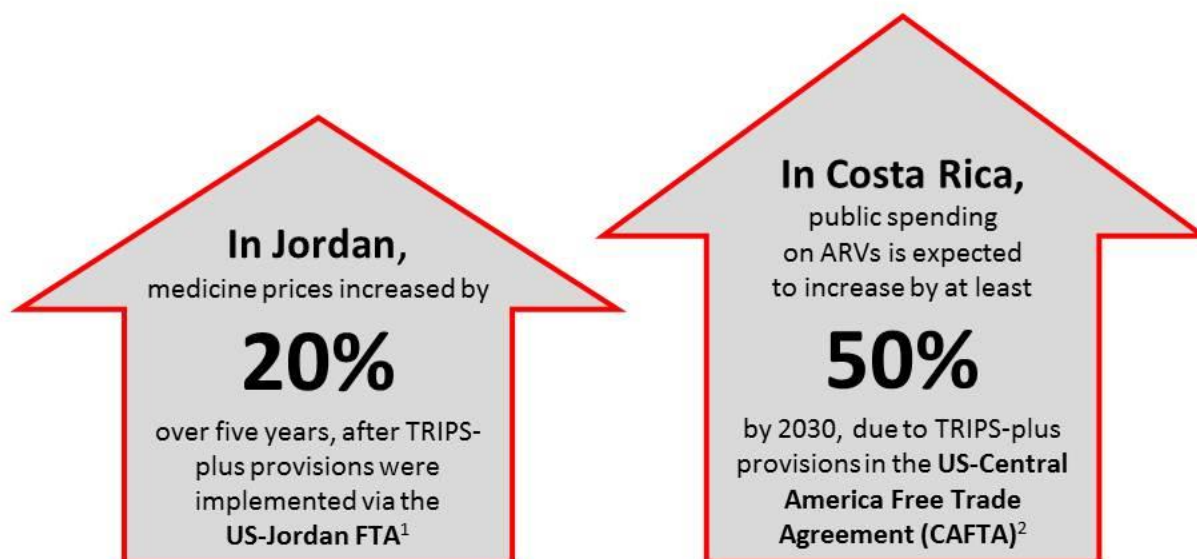
When the damaging impact of the TRIPS Agreement on public health started to become evident, WTO member states, including the U.S., signed the 2001 Doha Declaration on TRIPS and Public Health,¹² reaffirming the primacy of public health over trade and confirming that the TRIPS Agreement can and should be implemented in a manner supportive of WTO members’ right to promote access to medicines for all. The flexibilities allowed under TRIPS are recognized as important public policy and legal tools in the efforts to protect public health, and even wealthy nations like the U.S. have utilized these provisions.

“TRIPS-Plus” Provisions Roll Back Public Health Safeguards

However, over the last decade, many developing countries have come under pressure in trade negotiations to implement tougher IP rules, known as “TRIPS-plus” provisions, which expand patent monopolies, create new monopolies and preclude the use of flexibilities to protect public health.

The U.S. and the E.U. both have large pharmaceutical industries lobbying for stricter IP regulations, and these interests tip the balance away from public health protections. Furthermore, these provisions actually work to counter the efforts of global health programs, including those supported by the U.S. government and other TPP negotiating parties, which rely heavily on decreasing medicine prices brought about through generic competition.

The Impact of TRIPS-Plus Measures on Medicine Prices



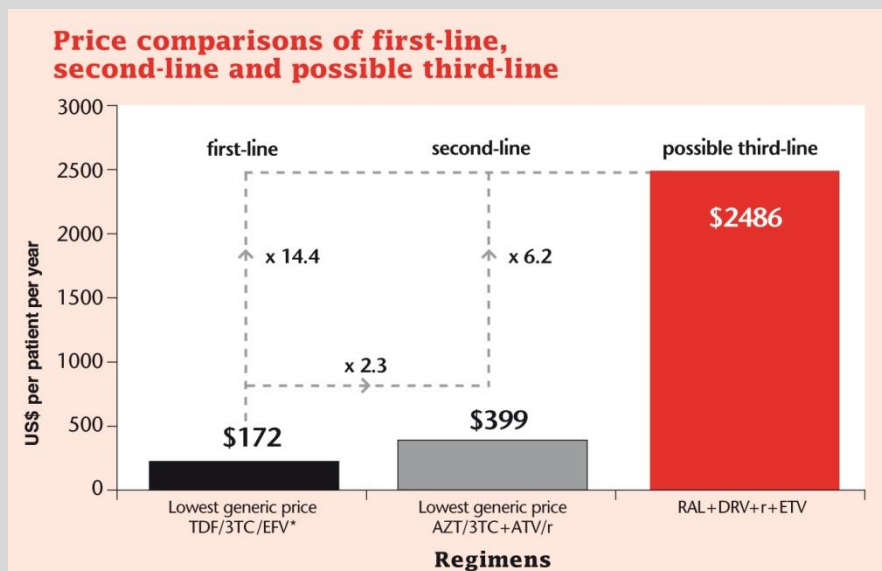
(1) OXFAM, *All Costs, No Benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines*, 2007; (2) UNDP Global Commission on HIV and the Law, July 2012

Next Generation HIV Drug Pricing Remains Prohibitive

Demand for second-line HIV treatments is growing fast: it is estimated that almost half a million people will need these medicines this year. Today, the most affordable second-line regimen is still twice as expensive as the recommended first-line regimen, and the price of a third-line regimen is more than 14 times higher than the recommended first-line regimen.

As most second- and third-line ARV drugs are still broadly protected by patents, further price reductions will require stronger competition via greater use of the flexibilities reiterated under the DOHA Declaration.

The TRIPS-plus provisions being pursued by the U.S. government in the TPP will make it more difficult to pursue these needed strategies in the future.



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

Lack of Medical Innovation to Meet Developing Country Needs

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 2006,¹³ “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 on innovation and access.¹⁴ 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. The CEWG final recommendation is for a binding global Research and Development Convention to secure appropriate funding, priority-setting and coordination to promote R&D needed to address the diseases that affect developing countries, and to break the link between the cost of R&D and the price of products.¹⁵

Today’s R&D Model Neglects Needs of the Poorest Patients

MSF is a humanitarian medical organization that needs and welcomes biomedical innovation to better treat our patients. MSF recognizes the importance of innovation and the need to finance medical research and development.

However, the reality is that intellectual property protection in the medical field keeps prices high and limits access to treatment, and furthermore does not stimulate innovation for many of the diseases affecting people in developing countries, where patients have limited purchasing power.

By seeking higher intellectual property norms in developing countries, the U.S. government is perpetuating a failed business model that links innovation costs to high prices, and does not adequately address the innovation needs of developing countries.

The U.S. Position Turns its Back on Previous U.S. Global Health Commitments

The leaked drafts of the U.S. negotiating positions for the TPP show that the U.S. is demanding aggressive intellectual property provisions that, if accepted, would trample public health safeguards enshrined in international law, in favor of offering enhanced patent and data protections to pharmaceutical companies that make it harder for TPP nations to gain access to more affordable generic drugs.

With these demands, the U.S. is turning its back on previous U.S. global health commitments, including:

- The 2001 WTO **Doha Declaration** reaffirming the primacy of public health over trade and confirming that the TRIPS Agreement, to which the U.S. is a party, can and should be implemented in a manner supportive access to medicines
- The 2008 World Health Assembly Resolution 61.21, the **Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property**, to which the U.S. agreed, which states that countries

are required to “take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than required by TRIPS”

- The **May 10, 2007 New Trade Policy¹⁶ (May 10 Agreement)**, in which Congress and the Bush administration reached a bipartisan agreement to include important public health safeguards in trade agreements with developing countries.¹⁷
- The **2011 UN Political Declaration on HIV/AIDS**, which recognizes the role that TRIPS flexibilities can play in increasing access to treatment, and calls on UN members to “ensure that intellectual property rights provisions in trade agreements do not undermine these existing flexibilities.”¹⁸

The May 10 Agreement represented “a fundamental shift in U.S. trade policy,”¹⁹ scaling back some of the harshest U.S. IP demands for developing countries in order to strike a better balance between protection of IP and public health needs.

However, the U.S. pharmaceutical industry has aggressively lobbied against the May 10 Agreement being applied to the TPP negotiations. Despite concerns from several members of Congress,²⁰ the USTR is shifting U.S. policy away from the May 10 Agreement and toward greater protection of IP rights for brand-name pharmaceutical companies in the developing world.

See Appendix A for a comparison of specific provisions between the May 10 Agreement and what the U.S. is demanding in the TPP.

The U.S.’s TPP Position Undermines Its Own Global Health Commitments

On the one hand, the U.S. has **declared ending the AIDS epidemic a policy goal** and affirmed its support for initiatives such as PEPFAR and the Global Fund.

On the other hand, the Administration is pursuing trade policies that will restrict access to affordable life-saving drugs.

Generic medicines significantly lower treatment costs and enable more lives to be saved. **Without continued access to new and forthcoming generic drugs, the anti-AIDS goals that the U.S. administration is championing will be unattainable.**

USTR’s TPP “Access to Medicines” Initiative is a Misnomer -- Proposal Actually Restricts Generic Competition --

In September 2011, the USTR proposed its “Trade Enhancing Access to Medicines” (TEAM) initiative for inclusion in the TPP, professedly aimed at “promoting access to medicines in TPP partner markets” via a “TPP access window” designed to “expedite access to innovative and generic medicines.”¹

In reality, the TEAM initiative falls far short of increasing access to medicines and will instead likely hinder generic competition. TEAM relies on weak voluntary measures to ostensibly speed the introduction of monopoly-protected pharmaceuticals in developing countries. For example, TEAM offers pharmaceutical firms an incentive of extended monopoly protection in developing countries where they register their intent to market their product. These extensions on drug monopolies would be granted using some of the TRIPS-plus provisions further explained below: patent term extensions, patent linkage and data exclusivity.

In other words, the TEAM initiative allows monopoly-protected manufacturers to ensure that generics remain blocked from developing countries for an extended period of time using TRIPS-plus provisions. As several key members of the U.S. Congress have noted, the “access window” would result in nothing other than “further delays in marketing of generic medicines.”²

(1) http://www.ustr.gov/webfm_send/3059, (2) <http://infojustice.org/wp-content/uploads/2011/09/Four-Democrat-Reps-10192011.pdf>

Specific U.S. Demands Threatening Access to Medicines

1) Broadening the scope of patentability: the U.S. wants to make it easier to patent minor modifications of old medicines, regardless of whether they offer any therapeutic benefits for patients

Existing Flexibility: The TRIPS agreement includes important flexibilities for governments to decide what type of pharmaceutical products deserve to be protected by patents in a given country. Essential requirements such as ‘novelty,’ ‘inventive step,’ and ‘industrial applicability’ can be defined by lawmakers in different countries so they are appropriate within the context of national circumstances (i.e., public health needs).

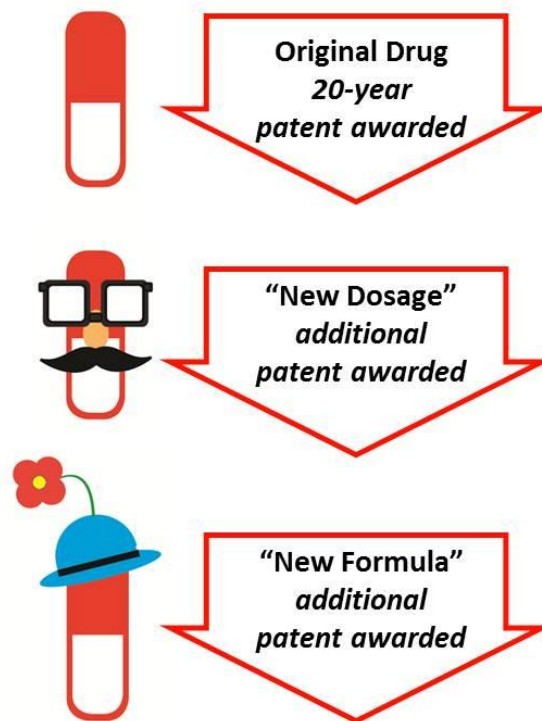
The TRIPS agreement allows countries to set their own patentability standards, and therefore developing countries like India, Philippines and Argentina have started defining grounds for rejecting a patent, for instance if the pharmaceutical substance claimed is just a new form of a known substance.

This flexibility is important because it allows governments to prohibit so-called “evergreening,” which enables pharmaceutical companies to extend the patent life and monopoly protection of old drugs simply by making minor modifications to existing formulations or dosages, without necessarily increasing the therapeutic efficacy for patients, or by identifying a new therapeutic use for an existing medicine.

What the U.S. Wants: The U.S. is seeking to erode this flexibility by requesting that TPP countries introduce new rules that would severely limit the ability of each country to define what is ‘patentable.’

For example, the USTR proposal for the TPP requests the patenting of a “new form, use or method of using” and “new formulations” of an existing product – even if there is no increase in efficacy – a provision that enables the practice of evergreening.²¹

How Does Evergreening Restrict Access to Medicines?



Affordable Generics Delayed

Evergreening is the practice whereby pharmaceutical firms extend monopoly protection, potentially indefinitely, by patenting modifications of an existing drug, delaying generic production of the drug beyond the original 20-year patent.

In addition, the U.S. seeks to require that plants and animals be patentable, as well as diagnostic, therapeutic, and surgical methods for the treatment of humans or animals.²² The TRIPS Agreement explicitly allows governments to exclude these inventions from patent protection. This provision goes beyond even what U.S. law allows, which exempts practicing surgeons from patent liability²³ and may preclude the patentability of some diagnostic methods.

Impact on Access to Medicines: Evergreening significantly affects access to medicines by allowing pharmaceutical companies to extend patent monopolies, potentially keep prices high indefinitely, and delay the arrival of more affordable generic medicines into the market.

The patentability of surgical methods without an exemption for practicing surgeons is especially relevant for MSF because it can raise doctors' liabilities if they are found to infringe a patent during the practice of a medical operation. This is the first time that the U.S. has included requirements to patent surgical methods in a trade agreement with developing countries.

Examples: How Expanding the Scope of Patentability Impacts Access to Medicines

Cancer patent application rejected

In 2006, the Indian patent office rejected Novartis' patent application for a life-saving anti-cancer drug imatinib mesylate on the grounds that the application claims a 'new form of a known substance' (Novartis' patent application was related to a particular crystal form of the salt of imatinib mesylate). This opened up generic competition, bringing down prices from over US \$2,400 per patient per year (ppy) to US \$200 ppy. Novartis appealed the decision and the case is currently pending an Indian Supreme Court hearing. The U.S.'s proposed IP provisions in the TPP would have forbidden India to reject the patent and allowed Novartis to continue evergreening its old drug.

HIV drug more expensive due to evergreening

GSK's original patents for Abacavir (ABC), an anti-retroviral, expired in 2009 and 2010, but the company has been able to extend its monopoly in many countries, including in developing countries, by filing for additional patents covering new formulations of the same drug.

In Malaysia, where GSK has been granted numerous patents for ABC, including for the "salt form" and pediatric variations of the drug, the public sector pays more than US \$1,200 ppy for pediatric ABC, more than 8 times the price of the generic version in other countries, which sells for as low as US \$139 ppy.

*Sources: <http://msfaccess.org/content/update-intellectual-property-battles-continue-india-novartis-trial-further-delayed>; MSF *Untangling the Web of Antiretroviral Price Reductions*, 14th Edition, July 2011.*

2) Restrictions on pre-grant patent oppositions: the U.S. wants to make it harder to challenge invalid or frivolous patents.

Existing Flexibility: The TRIPS agreement imposes no restrictions on filing an opposition to the granting of a patent – either before it has been granted (pre-grant opposition) or after (post-grant opposition).

What the U.S. Wants: The USTR's proposed provisions would forbid pre-grant oppositions in TPP countries, even those that already have the mechanism incorporated in their national laws.²⁴ This would mean that third parties will have to wait until the patent is granted to challenge a weak or invalid patent. Forbidding pre-grant patent oppositions not only makes it more costly and cumbersome to oppose a patent, but also deprives patent offices of the benefit of the expertise of third parties or even competitors to the applicant, who may be able to identify inaccuracies in the application before a patent is approved.

Impact on Access to Medicines: Pre-grant oppositions have successfully precluded granting of patents on several life-saving drugs, thus expanding access by allowing lower cost generics to enter the market. The use of this safeguard has resulted in rejection (or withdrawal) of key patent applications on important HIV/AIDS medications, including tenofovir, darunavir, nevirapine syrup and lopinavir/ritonavir, allowing generic companies in India to continue to manufacture, supply and export these HIV medicines to other developing countries. 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.

Example: How Pre-Grant Oppositions Can Preempt Granting of Invalid Patents

After India introduced patent protection for pharmaceutical products in 2005, Boehringer Ingelheim (BI) applied for a patent on the hemihydrate form pediatric suspension of Nevirapine (NVP), a widely-used HIV drug. Civil society groups filed a pre-grant opposition, and in June, 2008, the patent application was rejected by the Indian patent office, allowing for unrestricted competition on the pediatric formulation.

Tenofovir Disoproxil Fumarate (TDF) is a key component of the preferred WHO-recommended first-line HIV drug regimen. The basic patent has now expired in most countries, but Gilead has applied for additional patents. Thanks to generic production that started in India in 2005 and to the patent oppositions filed by civil society groups in 2006 and 2007 to safeguard production, the price of TDF fell dramatically between 2005 and 2010. In a major victory for access to medicines, in Brazil, civil society groups filed an opposition contesting Gilead's patent application in December 2006. In September 2008, the Brazilian patent office agreed and published the patent rejection. However, in January 2010, Gilead launched a legal challenge against the decision. Gilead also requested a divisional patent, which was opposed by civil society groups in a pre-grant opposition and which was rejected in May 2011.

Source for both: MSF Untanalina the Web of antiretroviral Price Reductions, 15th Edition, July 2012

3) Expanding data exclusivity: the U.S. is seeking to grant a backdoor route to monopoly status.

Existing Flexibility: Data exclusivity is not currently required in international law. The TRIPS agreement requires Member States to protect clinical data, but there is no obligation to grant any period of monopoly or exclusivity in the use of these data.

When a second entrant or generic manufacturer applies to register and sell a generic version of a previously-registered medicine, the manufacturer has to provide data showing that their product is bioequivalent to the original registration.²⁵ The drug regulatory agency already has the necessary clinical data for safety and efficacy, submitted by the originator, and must only assess if the generic version meets bioequivalence standards.

The introduction of data exclusivity prevents drug regulatory agencies from referring to existing clinical data to approve registration of generic versions of a drug by “locking up” the clinical data for a period of years, shutting down the entry of price-lowering generic competition for the duration. Data exclusivity essentially creates a new system for granting monopolies in order to prevent generic competition.

Generic manufacturers are forced to wait for the “data monopoly” period to end, even if the drug is unpatented, and even when a compulsory license is issued to override the patent. The only way a generic manufacturer can get a drug registered without access to existing clinical data is to repeat the clinical trials. However, duplicating clinical trials is not only extremely costly, but also unethical, since safety and efficacy has technically already been established, rendering further clinical trials medically unnecessary.

Many experts and UN agencies, including WHO, UNDP and UNAIDS, have recommended developing countries do not incorporate data exclusivity in their national laws (see Appendix B).

What the U.S. Wants: The USTR is currently proposing at least five years of data exclusivity for new chemical entities and at least three years of data exclusivity for drugs containing an already approved active ingredient.²⁶

Moreover, the placeholder text calling for data exclusivity for ‘biologic’ medicines in the TPP is especially alarming. Pharmaceutical firms are lobbying for the data exclusivity period for biologics to be set at a minimum of 12 years.²⁷ Because biologics are structured differently than traditional chemical medicines, second-entrant “generic” biologics are called ‘biosimilars’ or “follow-on biologics,” and require a different regulatory approval process. This would be the first time the U.S. has included a demand on biologics in a trade agreement, and if incorporated in the TPP, it would considerably delay the market entry of biosimilars.

It is unclear if the U.S. will renege on the public health safeguards specified in the May 10 Agreement, where exceptions were allowed in order to ensure governments could still effectively implement public health safeguards, including compulsory licenses, caps and concurrent periods of exclusivity (vs. effectively longer ‘consecutive’ periods of exclusivity).

Impact on Access to Medicines: Data exclusivity can delay the registration of generic or biosimilar versions of a medicine for many years. Some of the newest breakthrough medicines are biologics sold at extremely high prices. The introduction of data exclusivity for biologics will delay the introduction of affordable versions of these medications. The need for low-cost biosimilar alternatives to highly expensive lifesaving drugs, including pegylated interferon to treat Hepatitis C and herceptin to treat breast cancer, is acute.

Some Members of U.S. Congress have expressed formal opposition to the inclusion of any data exclusivity relating to biologics in the TPP.²⁸ In fact, the U.S itself is considering reducing its current data exclusivity provision for biologics from 12 to 7 years, in order to reduce the cost of medicines.²⁹ In addition, the Federal Trade Commission (FTC) has even recommended eliminating data exclusivity for biologics in the U.S.³⁰

Examples: How Data Exclusivity Keeps Prices High and Delays Generic Introduction

Data exclusivity, when implemented in national law, provides a distinct monopoly from patent rights that often results in high prices and a delay in market entry of generics.

As a part of the U.S.-Jordan FTA, Jordan implemented data exclusivity. A 2007 study by Oxfam⁽¹⁾ found that of 103 medicines registered and launched since 2001 that had no patent protection in Jordan, at least 79 percent had no competition from a generic equivalent as a consequence of data exclusivity. The study also found that prices of these medicines under data exclusivity were up to 800% higher than in neighboring Egypt.

A 2010 CPATH study⁽²⁾ determined that once Guatemala enacted data exclusivity, some medicine prices rose as much as 846 percent – even though just a handful of medicines were under patent protection.

Data exclusivity raises the price of medicines even when no patent exists. For example, in the U.S., the price of colchicine, a treatment used mainly for gout, rose more than 5000% after data exclusivity was enacted.⁽³⁾ Colchicine has been in use for thousands of years, costs almost nothing to produce, and cannot be patented. Therefore, generic formulations of the tablet have been widely available since the 19th century. However, a new monopoly on colchicine was created in 2009 when the FDA accepted clinical data from a one-week trial of the drug and granted data exclusivity to URL Pharma. URL Pharma subsequently sued to force other manufacturers off the market, and raised prices from \$0.09 to \$4.85 per pill.

Sources: (1) OXFAM, All Costs, No Benefits: How TRIPS-plus intellectual property rules in the U.S.-Jordan FTA affect access to medicines, 2007; (2) Kesselheim, A., Solomon, D., Incentives for Drug Development — Incentives for Drug Development — The Curious Case of Colchicine, N Engl J Med 2010; 362:2045-2047; (3) Shaffer, E., Brenner, J., A Trade Agreement’s Impact On Access To Generic Drugs, Health Aff September/October 2009 vol. 28 no. 5 w957-w968

4) Requesting patent term extensions: the U.S. is seeking to keep generic competitors out of the market, for longer

Existing Flexibility: The TRIPS Agreement requires patents to last 20 years, but imposes no additional provisions to extend monopoly rights further.

What the U.S. Wants: The U.S.'s proposed terms in the TPP would allow brand name pharmaceutical companies to lengthen this period by requiring countries to grant patent extensions of at least 5 years to compensate for administrative delays in the regulatory or patent approval process.³¹ Even though the May 10 Agreement recognized the harmful impact of patent term extensions on access to medicines, and made them voluntary/optional for countries negotiating trade agreements with the U.S., the U.S. is demanding that patent term extensions in the TPP be mandatory.

Impact on Access to Medicines: 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. Patent term extensions further delay the entry of generic medicines. Both the patent office and the drug regulatory authority have crucial roles to play in examining thousands of patent applications and making sure that registered medicines are safe and of good quality. Based on the provision that the US is proposing, the time taken to process patent and regulatory applications in developing countries could extend patent monopolies unduly.

5) Requesting patent linkage: the U.S. is seeking to turn drug regulatory authorities into 'patent police'

Existing Flexibility: Patent linkage is not only absent from international law, but is not even permitted in many developed countries. For example, most countries in Europe do not impose linkage between patent status and drug registration.

A drug's patent status and its registration status—its approval to market the drug in a particular country—are separate, each handled by separate government agencies with specific areas of competency. Patent offices assess whether a drug is innovative and novel enough to be patented, and national drug regulatory authorities assess whether a drug is of a high quality—safe and effective enough to be registered for use by the population they are responsible for.

Patent linkage is a TRIPS-plus provision that forces drug regulatory authorities to assess whether a generic drug could potentially infringe existing patents before approving its registration, but drug regulators are simply not equipped to evaluate patent validity; furthermore, it is up to the patent owner itself to identify and pursue potential patent infringements through the judiciary, a practice which ensures that the validity of a patent can be publicly questioned and held up to scrutiny before it is enforced.

What the U.S. Wants: The USTR has proposed that patent linkage be required of TPP countries, imposing more restrictive conditions for the registration of generic medicines in low-income nations than are found in Europe, and creating an important new and burdensome role for national regulatory authorities.

With this demand, the USTR is renegeing on the May 10 Agreement, which made patent linkage optional for countries negotiating trade agreements with the U.S.

Impact on Access to Medicines: Patent linkage provisions delay the market entry of generic medications. By requiring drug regulatory authorities to take on the responsibility of policing patents, this aggressive TRIPS-plus provision hinders generic drug registration while circumventing patent dispute processes between the patent holder and the patent authorities.

6) Imposing new forms of IP enforcement: the U.S. wants to allow customs officials to seize shipments of drugs on mere suspicion of IP infringement and to delay generic competition through threats of increased damages

Existing Flexibility: The TRIPS agreement allows for considerable flexibility in designing national mechanisms of IP enforcement and permits exclusion of border measures on patented products.

If pharmaceutical products are considered to be infringing trademarks, the TRIPS Agreement only requires governments to ensure customs officials can seize drugs if they are the product of willful and commercial scale actions (e.g. drugs that misrepresent their source and may have been purposefully adulterated and are dangerous for public health). Also, governments can limit damages or the availability of injunctions (which might otherwise prohibit a generic company from marketing a drug) in the interest of public health.

What the U.S. Wants: The U.S.'s proposed terms would eliminate some of these flexibilities. The U.S. is demanding that TPP countries implement and apply stronger enforcement measures than required by international law.

The U.S. is requesting that TPP countries grant customs officials the ex-officio right to detain shipments of medicines at the border, even for generic medicines in transit to developing countries, when they are suspected of civil, non-counterfeiting trademark infringement.³² But customs officials are not equipped to apply trademark law's complex multi-factor tests. The U.S. proposal conflates pure commercial trademark disputes and criminal offenses, such as production of counterfeit, falsified, or substandard medicines.³³ The result is a policy that could harm, rather than help, public health, by delaying legitimate medicines en route to people who need them in developing countries.

The US also seeks to require mandatory injunctions for alleged IP violations. This runs counter to provisions in TRIPS that allow for the possibility of judicially authorized licenses and royalty payments as damages. Furthermore, the U.S. is requesting TPP countries to mandate that judicial authorities consider valuing damages based on "the suggested retail price or other legitimate measure of value submitted by the right holder" in cases of infringement of intellectual property rights,"³⁴ a mechanism that strongly

Example: How New Forms of IP Enforcement Cause Unnecessary Drug Supply Interruptions

During 2008 and 2009, at least 19 shipments of generic medicines from India to other countries were impounded while in transit in Europe on grounds that the shipments were suspected of infringing trademark and patent rights in Europe. However, the shipments were bound for countries where the products would not infringe patent rights.

In one instance, German customs authorities wrongfully seized a drug shipment of "Amoxicillin" on the suspicion that it infringed the brand name "Amoxil" – the cargo was detained for four weeks while further investigation took place, eventually revealing that there was no trademark infringement at all.

In another instance, the Dutch customs authorities seized a shipment of the AIDS drug abacavir sulfate while it was en route (via Europe) from India to a Clinton Foundation project in Nigeria. The result was a disruption in the supply chain of legal generic drugs.

*Sources: WTO, [European Union and a Member State – Seizure Of Generic Drugs in Transit](#), May 19, 2010. Zarocostas, J., [Brazil and India file complaint against EU over seizure of generic drugs](#), *BMJ* 2010;340:c2672*

favors the rights holder and increases damage amounts. Each country should have the flexibility to individually determine the appropriate remedy and measure for damages for IP infringement.

Impact on Access to Medicines: Increased enforcement of IP laws has already been used to limit legitimate trade in generic medicines between developing countries. Extending IP enforcement rules beyond the enforcement measures required in the TRIPS agreement, and without safeguards against abuse, widens opportunities to disrupt legitimate trade in generic medicines. Customs and border officials often do not have the necessary expertise to make accurate assessments with regard to intellectual property disputes, yet will be granted the power to seize medicines on a mere suspicion or allegation of IP infringement. Unwarranted interception of legitimate in-transit pharmaceutical supplies can undermine legitimate trade in generic medicines. Furthermore, MSF purchases and stores medicines for use in our medical operations in different countries and such rules, if implemented, may affect our operations. If TPP countries agree to the U.S.'s proposal for valuing damages, their judiciaries will have their hands tied and will no longer be able to balance intellectual property rights with public health.

Enacting ACTA Provisions Through the Back Door Via TPP

Many have expressed concerns about the Anti-Counterfeiting Trade Agreement (ACTA) and the impact it could have on access to generic medicines. Although several countries signed the agreement, so far no signatory has ratified it, and in July 2012, the European Parliament voted by an impressive majority to reject it. In addition, the Australian Parliament's Joint Standing Committee on Treaties has cautioned against the ratification of ACTA.

ACTA was purported to protect against counterfeiting across a number of industries, including for medicines, where it was promoted as a way of blocking potentially harmful 'counterfeit' medicines. But the provisions in ACTA actually threatened fair, legitimate trade in generics, while failing to address the need to strengthen regulatory authorities in combating substandard medicines.

MSF strongly supports efforts to ensure that medicines meet accepted international standards of quality, safety, and efficacy; however ACTA's excessive enforcement provisions left too much room for error and did not address the underlying public health problem of poor quality, substandard medicines.

The numerous threats that ACTA would pose to access to medicines include:

- ACTA would impede access to generic medicines while extending IP protection and enforcement measures in ways that curb access to affordable treatment, to the detriment of patients and treatment providers alike
- ACTA would allow border detention of in-transit medicines destined for developing countries, which leaves legitimate trade in generic medicines open to unwarranted disruption
- The stringent provisions in ACTA would also target third parties – including treatment providers like MSF – by exposing them to the risk of punitive action in infringement allegations
- ACTA would be deterrent to generic medicine production and trade by shifting the risk of excessive punishments entirely on to generic manufacturers, and granting few protections against abuse
- ACTA is a cynical exploitation of concerns about unsafe medicines, and is not a legitimate response to the public health problem of substandard medicines

Yet similarly harmful provisions are still being pursued in the TPP. If they are accepted, the effect on access to medicines will be chilling.

Source: <http://www.msfaccess.org/content/acta-and-its-impact-access-medicines>

This briefing note has primarily addressed the U.S. government demands on patents and intellectual property, but the TPP contains other chapters that, if accepted, would also negatively affect access to medicines in developing countries. The following two provisions, from the pharmaceutical pricing and investment chapters, could have a detrimental effect on access to medicines.

7) Pharmaceutical pricing chapter: the U.S. is seeking to assist pharmaceutical companies in locking in high prices

According to the leaked text, the USTR's proposed terms would force government pharmaceutical reimbursement or price control programs that exist in some countries to reflect the "market value" of drugs, thereby increasing the purchase price and restricting the capacity of governments to negotiate discounts or price reductions.

The U.S. proposal for the TPP mandates that governments buy medicines at much higher fixed prices, allows pharmaceutical companies to be part of the decision making process, and even allows pharmaceutical firms to challenge government decisions. The TPP agreement would be the first trade agreement where the U.S. is known to be proposing a standard that would restrict the operation of non-discriminatory domestic pharmaceutical price policies in developing countries. And the U.S. is proposing these measures in an agreement it describes as having "global" and "gold standard" ambitions.

8) Investment chapter: the U.S. wants to allow pharmaceutical companies to sue governments and limit their ability to effectively set medicines prices

The leaked TPP investment chapter contains provisions that would give private corporations the right to sue governments if the regulatory environment negatively affects their "investments," including expected profits.

The definition given to 'investment' in the TPP encompasses intangible investments, including intellectual property.³⁵ Granting companies these rights could therefore undermine TPP governments' ability to issue regulations to protect public health and promote access to medicines, and expose them to lawsuits from corporations that claim their IP rights are being infringed upon by government action.

Example: Challenging Public Interest Regulations Through Investor-to-State Arbitration

Investor-state tribunals have proven to be extremely problematic, undermining legislative, administrative, and judicial decisions to protect other public health issues.

The tobacco company Philip Morris is currently capitalizing on investment rules in trade deals to sue Uruguay and Australia for introducing packaging laws banning branding on cigarette packaging as part of their public health campaigns against smoking. Philip Morris claims that by ensuring that public health warnings are included on cigarette packaging and removing branding from cigarette packaging, governments are infringing on the tobacco company's trademark and investment rights.

Sources: <http://www.bbc.co.uk/news/world-asia-15815311>,
<http://en.mercopress.com/2012/03/19/philip-morris-sues-uruguay-cigarette-labeling-claiming-violation-of-investment-treaty>.

This could happen if, for example, a government decided to regulate drug prices. A company could then claim that the government's action negatively impacts their 'investment' in the country.

To resolve disputes, the TPP proposal creates extra-judicial international investor-state tribunals that bypass national judicial systems and even WTO-based dispute settlement mechanisms, can override national laws and issue penalties for failure to comply with its rulings, and that make decisions via closed-door processes that are usually unappealable.

APPENDIX A: Summary of TRIPS, 2007 New Trade Policy, and TRIPS-plus policies

| Policy | TRIPS flexibilities for public health | 2007 New Trade Policy | U.S. "TRIPS-plus" proposals for TPP |
|-------------------------------|--|--|---|
| Scope of patentability | Countries have the right to define patentability criteria; for example, to only grant patents for truly innovative products and to exclude certain products from patentability | No mention | USTR leaked position expands scope of patentability to include: <ul style="list-style-type: none"> - new forms & uses, methods of using and new formulations even if no increase in efficacy ("evergreening" of old drugs) - patenting of plants & animals, and diagnostic, therapeutic, & surgical methods |
| Patent challenges | Countries have the right to create patent challenge mechanisms. The TRIPS agreement contains no limits on the possibility of pre- or post- grant patent challenges | No mention | USTR leaked position prohibits pre-grant patent challenges |
| Enforcement | Countries can define intellectual property enforcement mechanisms within broad confines of TRIPS agreement | No mention | USTR leaked position imposes new mechanisms of enforcement: <ul style="list-style-type: none"> - more lenient standards for seizures of drug shipments (even in transit countries when products are legal in origin & destination countries) - defines IP damages based on retail price of drugs - requires that patent validity is presumed until proven otherwise - requires injunctions in some cases |
| Data exclusivity | Countries have the right to define data protection provisions that do not grant market exclusivity or monopolies; data exclusivity is not included in the TRIPS agreement | Mandated, but for a maximum of five years; exceptions allowed for public health | USTR position requires that countries provide: <ul style="list-style-type: none"> - 5 years data exclusivity over clinical trial information relating to drugs containing new chemical entities - 3 years data exclusivity over clinical trial information relating to drugs containing already approved active ingredient - placeholder in text reserves space to include data exclusivity provision for biologics (potentially 12 years) |
| Patent term extensions | TRIPS agreement only requires 20-year patent terms; term extensions are not in the TRIPS agreement | Term extensions for regulatory delays are optional | USTR position requires countries to extend 20-year patent terms to compensate for delays in regulatory or patent approval processes |
| Patent linkage | Countries have the right to grant regulatory approval of generic medicines independent from patent status; patent linkage is not in the TRIPS agreement | The implementation of patent-linkage is optional | USTR position requires countries to mandate that regulatory authorities check for patent infringement before granting regulatory approval of a drug |
| Compulsory licenses | Countries can issue compulsory licenses and can authorize the use of a patented product without the authorization of the patent holder for a variety of reasons, including public health | Recognizing that data exclusivity can eliminate effectiveness of compulsory licenses by delaying entry of generics, a public health exception to data exclusivity is allowed | No mention in leaked USTR position, but several provisions could potentially make compulsory licenses ineffective |

APPENDIX B: What Others Are Saying About the TPP

Global Commission on HIV and the Law: Risks, Rights and Health, July 2012.³⁶

“Free trade agreements (FTAs) and economic partnership agreements (EPAs) containing TRIPS-plus standards also threaten access to medicines. A case in point is the United States–promoted Transpacific Partnership Agreement (TPPA). Among other terms friendly to the United States pharmaceutical industry, the proposed patenting standards would allow patenting of new forms, new uses and new formulation of existing medicine; extend patent terms; and restrict the use of price control mechanisms. In another example, the proposed EU-India FTA would shrink the latitude of countries to adopt policies promoting the production and distribution of generic medicines. The United States trade stance, which threatens access to affordable medicines for millions of the world’s poorest people, is egregious given President Barack Obama’s professed commitments to increased economic equality and access to health care in the United States. “

UNDP, UNAIDS Issue Brief, The Potential Impact of Free Trade Agreements on Public Health, 2012.³⁷

“Assertions are often made about the advantages of TRIPS-plus protection but there has been little evidence of the beneficial effects of TRIPS-plus measures either in the form of increased foreign investment or increased innovation.”

“To retain the benefits of TRIPS Agreement flexibilities, countries, at minimum should avoid entering into FTAs that contain TRIPS-plus obligations that can impact on pharmaceuticals’ price or availability.”

UNAIDS, UNDP, WHO Joint Policy Brief, Using TRIPS flexibilities to improve access to HIV treatment, 2011.³⁸

The document reiterates the WHO Global Strategy and Plan of Action recommendation that Member States *“take into account... the impact on public health when considering adoption or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights.”*

The document cites a number of TRIPS-plus provisions *“that may have an impact on public health or may hamper the use of TRIPS flexibilities, including: test data protection [data exclusivity]; requiring countries to loosen the criteria for patentability; providing for the possibility of extensions of terms for individual patents ... to compensate for delays in ... approval processes; and limiting the grounds under which a patent may be revoked.”*

The document recommends that *“high-income governments should ensure that free trade agreements with middle- or low-income countries comply with the principles of the Doha Declaration”*

Global Fund to Fight AIDS, Tuberculosis and Malaria: Report of the Market Dynamics and Commodities Ad Hoc Committee,³⁹ **May 11-12, 2011.**

The report expresses concern about the potential impact of the proposed EU-India FTA on prices of, and access to, HIV treatment. The report emphasized that countries should use TRIPS flexibilities to achieve the lowest possible prices for products of assured quality

UNAIDS Press Release, December 9, 2010: Trade agreements should not hinder efforts towards universal access to HIV prevention, treatment, care and support.⁴⁰

“In this current economic climate, resources for AIDS have already flattened and need for treatment continues to outstrip supply. Trade agreements that place additional burdens on the manufacture, import or export lifesaving medicines—so-called ‘TRIPS plus’ measures such as ‘data exclusivity’—and incorrect interpretations of the term ‘counterfeit’ should be avoided.”

UN Special Rapporteur, Annual Report to the Human Rights Council, A/HRC/11/12, March 2009.⁴¹

“These agreements are usually negotiated with little transparency or participation from the public, and often establish TRIPS-plus provisions. These provisions undermine the safeguards and flexibilities that developing countries sought to preserve under TRIPS. Studies indicate that TRIPS-plus standards increase medicine prices as they delay or restrict the introduction of generic competition.”

Some of the recommendations included:

“100. Developing countries and LDCs should establish high patentability standards and provide for exclusions from patentability, such as new forms and new or second uses, and combinations, in order to address evergreening and facilitate generic entry of medicines.

105. Developing countries and LDCs should establish liberal pre-grant, post-grant opposition and revocation procedures, which can be taken advantage of by all concerned stakeholders, including patients’ groups.

108. Developing countries and LDCs should not introduce TRIPS-plus standards in their national laws. Developed countries should not encourage developing countries and LDCs to enter into TRIPS-plus FTAs and should be mindful of actions which may infringe upon the right to health.”

WHO, Briefing Note: Access to Medicines, March 2006.⁴²

“From the perspective of public health and access to medicines, it is preferable not to grant data exclusivity. Moreover, there is no requirement under international law that countries grant data exclusivity; countries only have to provide for data protection” “TRIPS plus’ requirements have at times been incorporated in bilateral or regional free trade negotiations, in bilateral investment agreements and in other international agreements and treaties. From the perspective of access to medicines, this is a worrying trend; countries should therefore be vigilant and should not ‘trade away’ their people’s right to have access to medicines.”

U.S. Congressional Support for Ensuring Access to Medicines is Protected in the TPP:

Senator Bernie Sanders (I-VT): Letter to Ambassador Ron Kirk, December 1, 2011.⁴³

Senator Sanders objects to USTR’s position with regard to access to medicines in the TPP and the apparent retreat from the May 10th Agreement. Senator Sanders also objects to the secrecy of the negotiations and calls for the public release of the TPP negotiating texts.

“I join other member of Congress in calling for improvement of the USTR’s position in this negotiation, including the incorporation of the May 10 Agreement provisions.”

Senator notes that the USTR’s Trade Enhancing Access to Medicines (TEAM) approach is a “disingenuously named initiative [that] does not balance trade with access to medicines. Rather, it would erect even higher intellectual property barriers to affordable generic medicines for millions.”

10 Congressional Representatives: Letter to Ambassador Ron Kirk, August 2, 2011.⁴⁴

Members of Congress expressed concerns that the public health interests of developing countries are not being effectively addressed.

“We are concerned... that the balance is once again shifting away from... access to affordable medicines and towards the greater protection of intellectual property rights for brand-name pharmaceutical companies in the developing world, a move that would jeopardize treatment goals and millions of lives.”

“TRIPS-plus provisions in FTAs have been demonstrated to dramatically increase the cost of medicines in developing countries, pricing medicines out of reach of the poor and straining public health budgets.”

Representative Henry Waxman (D-CA), Representative Sander Levin (D-MI), Representative John Conyers Jr. (D-MI), Representative Jim McDermott (D-WA): Letter to Ambassador Ron Kirk, October 19, 2011.⁴⁵

Members of Congress ask the USTR to ensure that the TPP upholds U.S. commitments to safeguard access to medicines in the development world.

“We are concerned that some of the goals and approaches described as part of the new strategic initiative Trade Enhancing Access to Medicines (TEAM) could limit, rather than expand, access to medicines in poor countries... The best way to preserve our developing country trade partners’ access to medicines is to incorporate in the TPP the Bipartisan Agreement on Trade Policy of May 10, 2007... “There would be significant concern if action through TPP could delay access to generic medicines which may result in higher costs to the U.S. government to reach PEPFAR treatment goals or could result in removing patients from treatment.”

Representative John Lewis (D-GA), Representative Pete Stark (D-CA), Representative Charles Rangel (D-NY), Representative Earl Blumenauer (D-OR), Representative Llyod Doggett (D-TX): Letter to Ambassador Ron Kirk, September 8, 2011.⁴⁶

Members advocated for improved public health standards in TPP negotiations, especially relating to global health and access to medicines.

“The standards established by this agreement should reflect our shared goals to improve global health and access to medicines. The terms agreed to by Congress and President Bush on May 10, 2007 should be considered a non-negotiable starting point for the TPP negotiations.”

“...we have long urged an improved and transparent interagency process and structured consultations with public health interests regarding the potential impact of IP and pharmaceutical provisions on U.S. and global public health efforts.”

U.S. Congressional Support for Ensuring More Transparency in the TPP:

132 Congressional Members: Letter to Ambassador Ron Kirk, June 27, 2012.⁴⁷

Congressmen asked for more transparency in the TPP negotiations. Chief among their concerns was the lack of consultation with Congress.

“According to USTR statements, the TPP membership could ultimately include half of the nations in the world...We are troubled that important policy decisions are being made without full input from Congress... Under the trade advisory system, representatives from over 600 business interests have such access to both USTR negotiators and the negotiating text. However, American small business, civil society, and other interests who have a direct and long-term interest in the outcome of these negotiations have little meaningful input. In the past, most important U.S. trade agreement texts have not been made available until after they were signed and changes were all but impossible. If Congress and the public are not informed of the exact terms of the agreement until the conclusion of the process, then any opportunity for meaningful input is lost.”

Senator Sherrod Brown (D-OH), Senator Ronald Wyden (D-OR), Senator Jeff Merkley (D-OR), Senator Bob Menendez (D-NJ): Letter to Ambassador Ron Kirk,⁴⁸ **June 25, 2012, and Press Release,**⁴⁹ **June 27, 2012.**

Senators ask for greater congressional access to negotiations. From the press release:

“It’s troubling that corporate CEOs often have better access to information about trade negotiations than the American people’s elected representatives—or the American people themselves,” Brown said. “We must learn from the lessons of prior trade deals, and increase transparency when it comes to the

ongoing negotiations regarding the Trans-Pacific Partnership—an agreement that may become a template for all future trade agreements.”

From a [news article](#)⁵⁰ quoting Senator Wyden: “The majority of Congress is being kept in the dark as to the substance of the TPP negotiations, while representatives of U.S. corporations -- like Halliburton, Chevron, PhRMA, Comcast and the Motion Picture Association of America -- are being consulted and made privy to details of the agreement,” said Wyden.

Representative Darrell Issa (R-CA): [Letter to U.S. Trade Representative Ron Kirk, June 26, 2012.](#)⁵¹

Senator Issa requested permission to observe the TPP talks that took place in California in July, 2012, with the hope that observing the negotiating process would alleviate some concerns about the process through which the agreement is being negotiated. His request was ultimately [denied](#).⁵²

Senator Ronald Wyden (D-OR): [Legislation on trade agreement transparency, May 23, 2011.](#)⁵³

Wyden, chair of the Senate Finance Subcommittee on International Trade, introduced new legislation that would require the White House to share trade documents with all members of Congress and their qualified staff.

Representative Darrell Issa (R-CA): On May 15, 2012, House Oversight Committee Chairman Darrell Issa called for more transparency in the negotiation process and leaked one of the draft intellectual property chapter from the Trans-Pacific deal to the public on his [website](#).⁵⁴

Senator Al Franken (D-MN): [Letter to Ambassador Ron Kirk, May 8, 2012.](#)⁵⁵

Franken urges transparency on the TPP.

“As your office has stated, it may ultimately be the single largest trade agreement by volume in U.S. history. That makes it all the more important that the agreement be crafted in the most transparent and participatory manner possible... I therefore request that, to the greatest extent possible, you make the substance of the proposals you have tabled public and continue to do so at the conclusion of each negotiating round.”

Endnotes:

¹ <http://www.ustr.gov/about-us/press-office/press-releases/2009/november/ustr-news-kirk-comments-trans-pacific-partnership/>

² Leaked versions of TPP negotiating texts, available here: <http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf>, <http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>, <http://www.citizenstrade.org/ctc/wp-content/uploads/2012/06/tppinvestment.pdf>

³ <http://www.whitehouse.gov/the-press-office/2011/11/12/remarks-president-obama-apec-ceo-business-summit-qa>

⁴ See, for example, <http://keionline.org/tpp>, <http://citizen.org/tppa>

⁵ <http://www.ustr.gov/about-us/intergovernmental-affairs/advisory-committees>, <http://www.ita.doc.gov/itac/committees/itac03.asp> and <http://www.ita.doc.gov/itac/committees/itac15.asp>

⁶ <http://www.unaids.org/en/resources/campaigns/togetherwewillendaids/index.html>

⁷ 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. Available from:

<http://www.biomedcentral.com/1758-2652/content/13/1/35/>

⁸ <http://www.pepfar.gov/press/remarks/2011/160817.htm>

⁹ <http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf>, see also

<http://www.who.int/medicines/areas/policy/who-dap-98-9rev.pdf>

¹⁰ http://www.wto.org/english/docs_e/legal_e/27-trips.pdf

¹¹ http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2049_PolicyBrief_TRIPS_en.pdf

¹² http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.pdf

¹³ <http://www.who.int/intellectualproperty/en/>

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- ¹⁴ <http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf>
- ¹⁵ http://www.who.int/phi/news/cewg_2011/en/ and <http://www.msfacecess.org/content/how-global-rd-convention-could-fill-gaps-left-todays-medical-innovation-system>
- ¹⁶ <http://waysandmeans.house.gov/media/enewsletter/5-11-07/07%2005%2010%20New%20Trade%20Policy%20Outline.pdf>;
Also, analysis of the May 10 agreement: Jorge F. New U.S. trade policy: a turning point? J. Generic Medicines (2007);5:5-8.
- ¹⁷ http://www.ustr.gov/sites/default/files/uploads/factsheets/2007/asset_upload_file127_11319.pdf
- ¹⁸ U N 2011 Political Declaration on HIV and AIDS, Paragraph 71 a.
<http://www.unaids.org/en/aboutunaids/unitednationsdeclarationsandgoals/2011highlevelmeetingonaids/>
- ¹⁹ <http://waysandmeans.house.gov/media/enewsletter/5-11-07/07%2005%2010%20New%20Trade%20Policy%20Outline.pdf>
- ²⁰ <http://democrats.waysandmeans.house.gov/media/pdf/112/WaysMeansLettertoUSTR-TPPMay10.pdf>
- ²¹ Article 8.1, Leaked TPP IP Chapter (<http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>)
- ²² Article 8.2, Leaked TPP IP chapter (<http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>)
- ²³ 35 U.S.C. 287 §§ (c)(1)-(2) (2010).
- ²⁴ Article 8.7 Leaked TPP IP Chapter (<http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>) see also
Leaked US Paper on Eliminating Pre-Grant Opposition (<http://www.citizen.org/documents/Leaked-US-TPPA-paper-on-eliminating-pre-grant-opposition.pdf>).
- ²⁵ http://www.who.int/medicines/services/expertcommittees/pharmprep/QAS04_093Rev4_final.pdf
- ²⁶ Article 9(2)(c), Leaked TPP IP chapter (<http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf>)
- ²⁷ <http://www.pharmalot.com/2011/05/pharma-wants-12-years-data-protection-in-tpp-talks>
- ²⁸ http://www.henrywaxman.house.gov/UploadedFiles/TPP_Biologics_Letter_08-04-11.pdf
- ²⁹ <http://www.whitehouse.gov/sites/default/files/omb/budget/fy2012/assets/jointcommitteereport.pdf>
- ³⁰ Federal Trade Commission (FTC), Emerging Health Care Issues: Follow-on Biologic Drug Competition, June 2009.
- ³¹ Article 8(6)(b)-(c), Leaked TPP IP chapter (<http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf>)
- ³² Article 14.4, Leaked TPP IP chapter (<http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>)
- ³³ http://www.doctorswithoutborders.org/publications/reports/2011/2011Special301MSF_Final.pdf
- ³⁴ Article 12.3(b), Leaked TPP IP chapter (<http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf>)
- ³⁵ <http://www.citizenstrade.org/ctc/wp-content/uploads/2012/06/tppinvestment.pdf>
- ³⁶ <http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf>
- ³⁷ http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2012/JC2349_Issue_Brief_Free-Trade-Agreements_en.pdf
- ³⁸ http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2049_PolicyBrief_TRIPS_en.pdf
- ³⁹ http://www.theglobalfund.org/documents/board/23/BM23_09MDC_Report_en/
- ⁴⁰ <http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2010/december/20101209pstrips/>
- ⁴¹ <http://www2.ohchr.org/english/issues/health/right/annual.htm>
- ⁴² http://www.searo.who.int/LinkFiles/Global_Trade_and_Health_GTH_No3.pdf
- ⁴³ http://keionline.org/sites/default/files/Sen_Sanders_letter_to_USTR_TPP_negotiations_12-1-2011.pdf
- ⁴⁴ <http://infojustice.org/wp-content/uploads/2011/08/Ten-Representatives-on-TPP-08022011.pdf>
- ⁴⁵ <http://infojustice.org/wp-content/uploads/2011/09/Four-Democrat-Reps-10192011.pdf>
- ⁴⁶ <http://infojustice.org/wp-content/uploads/2011/09/Five-MOCs-September-8-2011.pdf>
- ⁴⁷ http://www.publicknowledge.org/files/TPP_Letter_FINAL.pdf
- ⁴⁸ <http://www.wyden.senate.gov/download/letter-to-ustr-kirk-demanding-transparency-in-international-talks-tpp>
- ⁴⁹ <http://www.brown.senate.gov/newsroom/press/release/with-trans-pacific-partnership-negotiations-set-to-continue-in-california-next-week-senators-call-for-increased-transparency-including-broader-consultation-on-internet-freedom>
- ⁵⁰ http://www.huffingtonpost.com/2012/05/23/trans-pacific-partnership-ron-wyden_n_1540984.html?ref=politics&ref=politics
- ⁵¹ http://issa.house.gov/images/stories/Letters/6-26-12_issa_letter_to_kirk_on_tpp_negotiation_attendance.pdf
- ⁵² http://issa.house.gov/index.php?option=com_content&view=article&id=984:congressman-issa-releases-statement-about-denial-of-admission-to-upcoming-trans-pacific-partnership-negotiations&catid=63:2011-press-releases
- ⁵³ http://www.huffingtonpost.com/2012/05/23/trans-pacific-partnership-ron-wyden_n_1540984.html?ref=politics&ref=politics
- ⁵⁴ http://issa.house.gov/index.php?option=com_content&view=article&id=976:issa-releases-the-trans-pacific-partnership-intellectual-property-rights-chapter-on-keepthewebopencom&catid=63:2011-press-releases
- ⁵⁵ <http://mnfairtradecoalition.org/uncategorized/sen-al-franken-urges-transparency-on-the-trans-pacific-partnership>