

The Transpacific Partnership Agreement and Fast Track bill threaten access to medicines and biomedical innovation

Executive summary

The Office of the United States Trade Representative (USTR) is currently negotiating the Trans-Pacific Partnership (TPP) agreement, a multilateral free trade agreement encompassing 12 countries in the Asia Pacific region. While US Trade officials brand this agreement as a model for 21st century trade, its deleterious effects go far beyond trade. If enacted in its current form, the TPP will have broad-reaching negative impacts on health and innovation, both at home and abroad. Disturbingly, these negotiations are also being held in private, away from public debate or legislative scrutiny. Universities Allied for Essential Medicines (UAEM) is a group of students in biomedical research, law and public health. Several provisions in the TPP will harm our ability to conduct cutting edge research, provide access to affordable care and enact sound public health policy.

According to the draft text leaked in Nov. 2013¹, the US supports proposals in the intellectual property (IP) and the investment chapters of the TPP that undermine individual countries' rights to use legal mechanisms to increase and/or defend access to lifesaving medications. These mechanisms are established in a previous international agreement, the "WTO Trade-Related Aspects of Intellectual Property Rights" (TRIPS)². The TPP grants pharmaceutical companies the ability to directly sue countries if they believe these public safeguards negatively impact their profits, via Investor-State Dispute Settlements (ISDS).

In light of the profound consequences of the TPP, the presence of an additional bill intended to impose sharp limits on debate and discussion around the TPP, the Bipartisan Congressional Trade Priorities Act of 2014 (also known as "The Fast Track Bill"), is troubling. Introduced in January of 2014 with the goal of implementing the TPP more efficiently, this bill grants the President unilateral control to sign the TPP, allows for TPP agreements to be viewed for only 90 days without amendment and with only twenty hours of debate time before voting and removes 'veto' power granted to Congress on trade agreements passed.

Both the TPP and Fast Track have the potential to impede progress set forth by programs such as USAID, PEPFAR, and the Global Fund by making drugs too expensive to keep these programs sustainable, in addition to the likelihood that the TPP would raise the cost of domestic health care. The TPP also bars mechanisms of open innovation, stifling future innovation.

Congress has an obligation to advocate for the interests of their constituents by protecting public health interests. Universities Allied for Essential Medicines (UAEM) urges Members of Congress to oppose the TPP, particularly on the grounds of its discussion of anti-access and anti-innovation mechanisms, including increased patent protection for biomedical technology and ISDS. We also urge Members of Congress to oppose the TPP on the grounds of lack of transparency.

Background

Universities Allied for Essential Medicines (UAEM) is a global network of medical, law, and biomedical research students. We work to ensure that life-saving medicines – especially those discovered at universities with public funds – are affordable and accessible to patients. UAEM students believe that the Trans-Pacific Partnership (TPP) should not jeopardize access to affordable treatment. Specifically, we are deeply concerned about the excessively stringent and counter-productive terms within in the IP chapter.

TPP: Patent extension putting the price of health out of reach

Billions of people lack access to life-saving medicines because of their excessively high cost. Millions more become impoverished paying for patent-monopolized treatments³. This tragedy is not specific to low and middle-income countries (LMIC). Americans pay the highest prices in the world for prescription drugs at a cost of approximately \$325 billion per year. Californian Democratic representative, Henry Waxman, recently challenged these skyrocketing prices by questioning Gilead’s price of \$84,000 (USD) for its new hepatitis C drug, Sovaldi⁴.

While the traditional patent system granted inventors limited monopolies as a reward and incentive for developing truly innovative products; new IP mechanisms proposed in the TPP, such as patent “evergreening” or extension of a patent life beyond the original 20 year term, allow unnecessarily high prices for name-brand medications for longer terms. Moreover, these patent term extensions are not granted on grounds of efficacy, increasing price without increased public benefit.

Generic competition is the only proven method to reduce pharmaceutical prices.⁵ Generic drug competition reduced the price of first line HIV anti-retrovirals (ARV) 99% in the last decade. The TPP’s long-term IP protections will postpone the introduction of generic drugs to the market at the cost of lives. Contrary to industry perspectives, there is no verifiable evidence that lowering the prohibitively high cost of medicines will jeopardize drug research⁵. Countries where drug prices are regulated have not resulted in a reduction of their domestic drug research⁶.

TPP: Hindering access to critical research and education

The TPP harbors language that threatens fair-use laws indispensable for research and education. As in the information-technology sector, open-access and collaborative R&D models have opened new avenues of innovation in biomedical research. Many cutting-edge health research institutions, including universities and product development partnerships (PDPs), are using open-knowledge models to pursue research projects neglected by traditional IP-driven R&D – particularly research on neglected and orphan diseases. The TPP, as currently written, would undermine progress on open knowledge sharing in the scientific community, including the efforts of Drugs for Neglected Diseases Initiative (DNDi). DNDi has developed six new treatments in nine years for just US\$ 160 million using collaborative research methods and open-access IP⁷.

TPP: Broken promises

The US has repeatedly committed to improving global health. Former secretary of State Hillary Clinton reaffirmed the US's commitment to achieve an 'AIDS-Free generation'⁸. In 2014 alone, the United States government will contribute \$9.1 billion towards Global Health initiatives such as PEPFAR, USAID and the Global Fund⁹. These programs also work to procure life-saving medicines. Increasing the cost of medicines will dramatically decrease their impact and help fewer people.

As a WTO member, the US signed the Doha Declaration on the TRIPS agreement and public health. It therefore recognizes that all member states are free to make full use of TRIPS 'flexibilities' to ensure that trade-related IP policies do not endanger public health. Moreover, the previous American administration passed a bipartisan bill known as 'the May 10th agreement' that moves trade agreements away from imposing harsh IP provisions on certain developing countries.

The provisions in the TPP erode both domestic and international public health safeguards and directly undermine the United State's commitments to innovation and global and public health. UAEM students urge negotiators to acknowledge and incorporate the lessons learned from the global fight to provide treatment for HIV/AIDS to reject the current TPP and commit to sensible, balanced agreements that enable access to affordable medicines for all.

As students invested in careers in biomedical research, law and public health, we are driven to improve access

Effects of the Bipartisan Congressional Trade Priorities Act of 2014 (Fast Track) on the TPP

Under the Trade Priority Act, or "Fast Track", the President has the authority to choose negotiation partners and negotiate trade agreements without consulting congress, allowing private consultants from industry to write provisions within the agreement. A trade agreement can then move through the Fast Track process, disallowing amendments to the bill from Congress, to be followed by an up/down vote, not subject to veto.

Although the intent behind Fast Track is to obtain "more open, equitable, and reciprocal market access" and reduce trade barriers, it will do so in a nontransparent way. The bill also pushes for strengthened intellectual property rights, which stands contrary to a stated TPP aim: to respect the Doha Declaration of the TRIPS Agreement. In addition, allowing unilateral control by the executive branch ignores the constitutional power of Congress over trade agreements.

Fast Track will allow for the quick and undemocratic processing of the TPP as it hands over congressional checks and balances to the executive office:

- It will allow committees to view, but not amend trade agreement draft text
- The president will have unilateral control of the contents of a trade agreement
- The bill directly grandfathers in the TPP to avoid confrontation regarding the non-democratic process by which the text was established.

The bill faces tough opposition from Democrats and Republicans

- 151 Democrats signed on to a letter opposing the Fast Track authority that was sent to President Obama in November (Rosa DeLauro, D-CT).
- The Ways and Means Democrats submitted a letter in opposition to the Fast Track process (Mike Thompson, D-CA; Earl Blumenauer, D-OR).
- 27 Republicans have sent two letters disapproving of Fast Track to President Obama.

to biomedical technologies. Therefore, Universities Allied for Essential Medicines **urges Members of Congress to oppose the TPP** on the grounds that **the TPP will:**

- **Jeopardize access to affordable medicines**

The TPP contains the following specific damaging provisions that will undermine public health safe guards and delay the entry of generic drugs, decreasing access to medicines:

- Data exclusivity: Clinical trial data is covered under intellectual property, even though it should not fit the definition of patentable innovation.
- Patent term extensions or “Evergreening”: Extending patent monopolies and keeping affordable generic drugs from entering markets for much longer.
- Lowering the bar of patentability: Extending patent monopolies on old drugs and creating barriers for meaningful medical breakthroughs.
- Patenting of surgical methods: Patenting of surgical procedures, a practice viewed as unethical by multiple civil society actors¹¹, will make doctors liable to patent infringement and place undue burden on public health care systems of TPP countries.
- Investor state dispute settlements: This will allow companies to directly sue governments in nontransparent courts when they do not agree with domestic IP and patent decisions.

- **Suppress innovation and academic/medical research**

Threatening fair use laws and strengthening IP in research products will establish significant barriers against collaborative efforts and undermine university research and teaching. These provisions will only exacerbate the lack of innovation focused on meeting the needs of developing countries.

- **Undermine US global health commitments**

The US has made numerous commitments to improving global and public health in addition to investing billions of dollars towards to this end. The text in the TPP conflicts with the Doha Declaration and ‘May 10th agreement’ and will negatively impact AIDS treatment programs.

- **Obscure the democratic process, excluding congressional/public participation**

TPP negotiators must release the TPP ongoing draft text. TPP negotiations are being held privately, with minimal input or scrutiny from the public and limited congressional access, while over 600 corporate advisors have influence over the negotiation. This will undoubtedly skew the text. Hundreds of legislators across negotiating countries, including 132 United States Congressmen, have called for the release of the draft text¹⁰. Additionally, we urge congress to oppose the “Fast Track” bill, which circumvents congressional checks and balances.

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