

# Trans-Pacific Partnership: Curbing Access to Medicines Now and in the Future

## Overview

The Trans-Pacific Partnership (TPP) is currently being negotiated among 12 Pacific Rim countries: Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States, and Vietnam. If passed, it will become the largest U.S. free trade agreement (FTA) in history. It is anticipated that the agreement will expand existing intellectual property (IP) protections on pharmaceutical products, which will ultimately impede access to affordable generic medicines for diseases such as HIV/AIDS, cancer, tuberculosis, and hepatitis C.<sup>1</sup>

The IP provisions under consideration go well beyond the standards established by the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TPP continues a pattern of incrementally increasing IP protections for pharmaceuticals beyond those enshrined in recently negotiated FTAs. These repeated measures to extend IP protections result in a decline in generic competition and an increase in drug costs for those who can least afford them, and set dangerous precedents for future FTAs.

## Encroachment of TRIPS-Plus Provisions in FTAs

All member nations of the WTO are required to consent to a core set of agreements as a condition of membership. One of these is the TRIPS agreement, which establishes IP protection standards that include patent protection for pharmaceutical products for a minimum of 20 years.<sup>2</sup>

Since TRIPS came into effect in 1995, its IP standards have been progressively augmented and enhanced through bilateral and multilateral FTAs in what are known as "TRIPS-plus provisions." Patent protections for pharmaceutical products have been specifically highlighted in TRIPS-plus provisions in ways that are detrimental to generic access to drugs in developing countries. While amfAR fully recognizes the important role that IP plays in incentivizing investment in lifesaving medicines, the precise

## Summary

- **Background:** The Trans-Pacific Partnership (TPP) is likely to become the largest U.S. free trade agreement (FTA) in history.
- **The Issue:** Leaked texts of the proposed TPP reveal that it will expand existing intellectual property (IP) protections on pharmaceutical products, which will compromise access to affordable generic medicines for diseases such as HIV/AIDS, cancer, tuberculosis, and hepatitis C. The TPP goes even further than previous FTAs in increasing these IP protections.
- **amfAR's View:** By providing avenues for pharmaceutical companies to extend IP protection beyond what is required by current international standards, the TPP could greatly delay the entrance of generic competition for much-needed medicines and keep prices high. Doing so would continue an unacceptable and dangerous trend of irrevocable expansion of IP protections at the expense of access to medicines and would serve as a justification for even more aggressive measures in future FTAs.

levels of protection necessary to adequately support this research and development are highly debatable. The history of drug pricing has been fraught with unethical pricing demands from innovator pharmaceutical companies—as evidenced most recently with new treatments for hepatitis C.<sup>3</sup>

In the proposed TPP, there are several provisions that once again go beyond the requirements of TRIPS to the detriment

of access to medicines and continue the trend of increasing IP protections beyond those established by previous FTAs (as shown in Table 1):

- **Patent Term Extensions** – The proposed TPP requires all countries to offer patent extensions for pharmaceutical products to compensate for “unreasonable delays” in either granting the patent or approving the drug for marketing. Such terms have been common in FTAs in the past, but **the TPP weakens the required justification for what constitutes an “unreasonable delay,” making it easier for pharmaceutical companies to demand longer patent extensions and further delay the entrance of generic competition.**<sup>4</sup>

**“This isn’t a partisan issue... the only winners will be multinational corporations.”**

— Senator Elizabeth Warren

*Washington Post* editorial, February 25, 2015

- **Data Exclusivity** – Data exclusivity periods prevent drug safety regulators from using existing clinical trial data to give market approval to generic or biosimilar versions of the same drugs. They thus prevent generic drugs from entering the market, as they cannot be approved in the absence of safety and efficacy data. Furthermore, generic companies may be prohibited from developing their own clinical safety data, since it may be unethical to engage in medical research on patients in cases where existing clinical trials have already established the benefits of a new treatment.<sup>5</sup>

Importantly, data exclusivity periods apply even in the event that there is no patent protection available for a drug in a given country. **Moreover, the proposed TPP extends data exclusivity protection not only to new pharmaceutical products, but also to existing products that are being re-purposed for new clinical uses.**<sup>6</sup>

- **Biological Products** – Biological products are medical commodities developed through biological methods rather than synthetic chemical processes. Existing biological products include vaccines, blood and blood components, and gene therapies, among others. Because replication of biologics is more complex than synthetic manufacturing and there has been no process for proving the equivalence (or comparability) of different biological products, they have historically not faced generic competition. However, as part of the Patient Protection and Affordable Care Act (ACA), the Food and Drug Administration (FDA) was granted authority to approve biosimilar generics for patient use if generic

manufacturers could prove the safety and equivalence of their products.<sup>7</sup> The first generic biologic in the U.S. was approved in March 2015.<sup>8</sup>

As part of the ACA, innovator biological companies were granted a data exclusivity period of 12 years from the time a product is approved for market in the U.S.<sup>9</sup> There is evidence to suggest that the U.S. is pushing for the same period in the TPP, which is longer than in any other TPP negotiating country.<sup>10</sup> Such a level of protection may not only set the standard for countries directly involved in the TPP—including blocking any effort to lower the level of protection in the U.S. to seven years, as the White House has proposed<sup>11</sup>—but also for other drug regulators in low- and middle-income countries looking to establish procedures for generic biologics. **It could also undermine the entrance of generic biologics into the market—including future vaccines.** While IP protections for biological innovations can be useful to incentivize research and development, given the newness of approving generic biologics it is premature to lock in levels of protection before the market has developed.

- **Presumption of Validity** – The proposed TPP would require courts to grant a “presumption of validity” to patents if the country’s patent office has issued a patent.<sup>12</sup> This presumption reverses the burden of responsibility in a court proceeding, requiring an applicant to prove that the patent was *invalid*, rather than requiring the patent holder to prove the patent’s validity. **This imposes a greater burden on civil society organizations or generic manufacturers when challenging the validity of patents in court. Such court challenges have proved successful in increasing generic competition in the past.**<sup>13</sup>
- **Scope of Patentability** – Several provisions of the proposed TPP expand the scope of what is considered a patentable invention, including plants and animals.<sup>14</sup> In the original TRIPS agreement, these categories of invention were specifically excluded from the requirement of patentability.<sup>15</sup>

More importantly, **the TPP requires that countries provide patent protection to “any new uses or methods of using a known product.”**<sup>16</sup> **Such provisions have been used to continually extend periods of patentability through a practice known as “evergreening,” in which minor changes are made to existing patented drugs in order to justify a new patent and extend the period of market exclusivity and prevent generic production.** In many cases, the “new use” is barely distinguishable from the prior use of the drug, yet it allows the company to obtain the same level of new patent protection.

**Table 1. Intellectual Property Provisions of the TPP and Recent Free Trade Agreements**

  TRIPS-equivalent — Provisions that are equivalent to those in the TRIPS Agreement  
  TRIPS-plus — Provisions that go beyond TRIPS levels of protection  
  Enhanced TRIPS-plus — Provisions that go even further than other existing “TRIPS-plus” provisions, establishing the strongest IP protections in any of the FTAs evaluated

	Trans-Pacific Partnership (2015) <sup>18</sup>	South Korea (KORUS FTA) (2012) <sup>19</sup>	Colombia Free Trade Agreement (2012) <sup>20</sup>	Panama Free Trade Agreement (2012) <sup>21</sup>	Peru Free Trade Agreement (2009) <sup>22</sup>	Dominican Republic-Central America Free Trade Agreement (2005) <sup>23</sup>	
<b>TRIPS-PLUS PROVISION</b>	Patent protection for plants <sup>24</sup>	Cannot exclude from patentability	Cannot exclude from patentability	Requires countries to make all reasonable efforts to make patent protection for plants available.	Requires countries to make all reasonable efforts to make patent protection for plants available.	Requires countries to make all reasonable efforts to make patent protection for plants available.	
	Patent protection for animals	Cannot exclude from patentability	Cannot exclude from patentability	Requires countries that already have patent protections for animals to maintain those protections.	Requires countries that already have patent protections for animals to maintain those protections.	Requires countries that already have patent protections for animals to maintain those protections.	
	Patents for “new uses” of existing products	Requires patents be available for new uses or methods of using a known product.  Prohibits having an “enhanced efficacy” requirement for patentability of new uses.	Requires patents be available for new uses or methods of using a known product.	Can be excluded from patentability.	Can be excluded from patentability.	Can be excluded from patentability.	Can be excluded from patentability.
	Patent extension: Unreasonable delays in granting patent by the patent office	Defines unreasonable delay as four years from filing date or two years from request for examination, whichever is longer.	Defines unreasonable delay as four years from filing date or two years from request for examination, whichever is longer.	Defines unreasonable delay as five years from filing date or three years from request for examination, whichever is longer.	Defines unreasonable delay as five years from filing date or three years from request for examination, whichever is longer.	Defines unreasonable delay as five years from filing date or three years from request for examination, whichever is longer.	Defines unreasonable delay as five years from filing date or three years from request for examination, whichever is longer.
	Patent extension: Unreasonable delays in granting marketing approval	No definition of unreasonable delay.  Limits the term of extension to five years and only on new pharmaceutical products (not new use).	No definition of unreasonable delay.  No limit on term of extension.	No definition of unreasonable delay.  No limit on term of extension.	No definition of unreasonable delay.  No limit on term of extension.	No definition of unreasonable delay.  No limit on term of extension.	No definition of unreasonable delay.  No limit on term of extension.
	Data Exclusivity: New pharmaceutical products	Five years from date of approval.  When relying on approval from another party country: Five years from date of approval in a new country.	Five years from date of approval.  When relying on approval from another party country: Five years from date of approval in a new country.	Five years from date of approval.  When relying on approval from another party country: If marketing approval granted within six months, five years from date of approval in first party country that granted approval.	Five years from date of approval.  When relying on approval from another party country: If marketing approval granted within six months, five years from date of approval in first party country that granted approval.	Five years from date of approval.  When relying on approval from another party country: If marketing approval granted within six months, five years from date of approval in first party country that granted approval.	Five years from date of approval.  When relying on approval from another party country: Five years from date of approval in new country.
	Data Exclusivity: New use for pharmaceutical products	Three years from date of approval.	Three years from date of approval.	No protection	No protection	No protection	No protection
	Biologics	Proposed language includes up to 12 years of protection.	No protection	No protection	No protection	No protection	No protection
Presumption of validity on granted patents	Yes	Yes	No	No	No	Yes	

Indeed, the proposed TPP goes further than any previous FTA to specify that patents cannot be rejected “solely on the basis that the product did not result in an enhanced efficacy.”<sup>17</sup> The requirement of “enhanced efficacy” has been a key provision of Indian patent law to discourage low-quality patents and “evergreening” practices.

Combined, these provisions constitute a considerable expansion of IP protections for pharmaceutical products that would constrain generic production and limit access to medicines.

### The Importance of Accessing Generic Medicines to Achieve an AIDS-Free Generation

**Our gains in reducing global HIV infections would never have been realized if the proposed provisions under the TPP were the intellectual property standard in 2001**

According to the WHO, of the 12.9 million people living with HIV who were receiving antiretroviral therapy (ART) at the end of 2013, 11.7 million were in low- and middle-income countries, including 740,000 children.<sup>25</sup> This massive expansion of ART has only been realized because of generic competition and the scale of production made possible by the

development of broad HIV treatment programs. Developing countries, the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), the Global Fund to Fight AIDS, Tuberculosis and Malaria, UNITAID, and other global HIV programs have been and will remain dependent on generic medicines to scale up treatment to the millions more who need it today.

The global community would never have achieved its successes in addressing the HIV epidemic if the terms of the proposed TPP were the international standard in 2001. The provisions expected to be enshrined in it would have altered the course of HIV programs and prevented India (and others) from supplying generic versions of on-patent medication to the hardest hit countries. The HIV epidemic today would look decidedly different, more desperate, and more fatal.

Though there is evidence that inclusion of TRIPS-plus provisions in FTAs has led to the withdrawal of generics from the market in the past, the extent to which the TPP will have a direct impact on the availability of the existing array of generic

HIV treatments is unclear.<sup>26</sup> Regardless, health systems in developing countries could lose access to generic competition in the context of new pharmaceutical products should the TPP’s provisions become standard in future FTAs, such as the proposed Regional Comprehensive Economic Partnership (RCEP) discussed below. This is true even for drugs that do not meet patentability standards under a country’s own domestic laws. And it is true not only for HIV, but for other diseases as well, such as tuberculosis, hepatitis, malaria, and various cancers.

### What We All Would Lose Under the TPP

The future availability of affordable generic medicines is being threatened by unnecessary attempts to strengthen IP protections on pharmaceuticals, which undermine the global HIV response and healthcare delivery in developing countries.

There are several issues in the TPP that raise serious concerns.

#### Direct Effects of the TPP

It must be acknowledged that the direct effects of the TPP will primarily be limited to its signatory countries. Most of them— with the possible exception of Vietnam—are economically stable and unlikely to see immediate dramatic ramifications in terms of access to medicines.

That said, the future stability and availability of HIV (and other) treatment programs may be hampered by delaying and reducing generic competition in these countries. New medications, such as long-acting antiretrovirals, have the potential to revolutionize HIV treatment programs, but the affordability of such drugs will remain suspect in middle-income countries. This is particularly true when considering the expanded scope of patentability on drugs that may significantly increase the time it takes for generics to be allowed on the market.

Additionally, other countries could sign on to the TPP after the agreement is finalized, thus expanding its direct impact on global access.

#### Anti-Democratic Levels of Secrecy and Transparency

Two processes are working together to make public engagement with the TPP profoundly undemocratic: 1) the terms of the treaty are being negotiated entirely in secret; and 2) the Administration and the U.S. Congress may use Trade Promotion Authority (also called “Fast Track Authority”) for passing the TPP.

On secrecy, the only public access to the proposed terms of the TPP has been through unauthorized leaked documents from WikiLeaks. Restricting access to the proposed terms prevents the public from engaging on the full substance of the agreement and means that the first public release of the terms will not occur until the text is essentially finalized and put before the U.S. Congress for debate and approval. Even members of Congress do not have access to the negotiated agreement despite the fact that full access has been provided to Industry Trade Advisory Committees, whose membership comprises many of the industries that stand to benefit from approving the TPP, including pharmaceutical companies.<sup>27</sup>

In combination with the secret negotiations, the President is seeking Fast Track Authority for passing the TPP.<sup>28</sup> Fast Track Authority means that no amendments to the agreement would be permitted by the Congress, which would only hold an “up or down” vote on the TPP as a whole. As such, any concerns with individual chapters of the agreement would have to justify a wholesale rejection of the TPP, which is highly unlikely.

**“Some matters pushed by the business community have little or nothing to do with the interests of the vast majority of U.S. workers and should not be emphasized. These include [efforts to] extend and strengthen patent protections...”**

— Lawrence Summers, Harvard University professor former U.S. Treasury Secretary (1999–2001) and White House economic advisor (2009–2010) *Washington Post* editorial, March 8, 2015

The legislation to grant Fast Track Authority has already been introduced and has cleared the Senate Finance Committee.<sup>29</sup> Similar legislation has been introduced in the House. While a period of public disclosure is built into the legislation, that public disclosure only takes place essentially after the terms have already been finalized.<sup>30</sup>

It should be noted that Fast Track Authority is not unusual for passing trade agreements. It has been commonly used since the 1970s and has facilitated the passage of virtually all FTAs involving the U.S. in recent years.

While secret negotiations or Fast Track Authority may be justifiable independent of each other, combined they prevent the public from having an opportunity for detailed engagement. If negotiations are held in secret but Congress

maintains the authority to make amendments to the TPP, the public can engage with their representatives to propose such amendments. Conversely, with Fast Track Authority alone, the terms of the TPP would be public well in advance of the final text being negotiated, enabling the public to comment without having to rely on unofficial and inherently unreliable (or outdated) leaks of the text.

A free trade agreement that impacts countless lives should be available to all so that legitimate concerns that could positively affect the outcome of the agreement can be raised. Doing otherwise is anti-democratic.

### Setting Precedents

The history of FTAs shows that the provisions that are agreed to eventually become standards that are incorporated into and built on in future FTAs (Table 1). In the case of IP, these provisions nearly universally enhance IP protections for pharmaceuticals rather than returning them to previous standards.

Examining the text of the 2012 FTA with South Korea<sup>31</sup> alongside the leaked text of the proposed TPP<sup>32</sup> is revealing in this regard. Many of the provisions in the IP chapter of the TPP that have been proposed by the U.S.—such as those on data exclusivity periods—are identical to the provisions that were negotiated with South Korea, just as many of the terms in the FTA with South Korea came from FTAs that pre-dated it or were negotiated alongside it.

This trend will likely continue, meaning that the terms of the TPP are unlikely to stay only within the borders of the countries currently involved in the negotiations. Instead they will be used as a template for enhancing IP protections in future FTAs. There is already concern that South Korea, Japan, and others are proposing IP standards similar to the TPP in ongoing negotiations for the Regional Comprehensive Economic Partnership, a proposed FTA involving 16 countries including India, the world’s largest generic manufacturing country.<sup>33</sup>

Importantly, these agreements that may have profound effects on access to medicines in developing countries do not allow those countries to provide feedback into negotiations that may very well harm their interests. While the TPP continues to include language enabling the use of flexibilities in the TRIPS agreement for developing countries and for public health purposes, the breadth and utility of some of these flexibilities—such as determining the scope of patentability—are specifically undermined by the TPP.<sup>34</sup>

### Impact on the International Development Community

The development community has struggled with the issues of access to medicines and drug pricing for middle-income countries. Although middle-income countries can reasonably be expected to pay for medicines at a rate commensurate with their level of economic development, public health need, and other factors, no harmonized system exists for establishing such a system. Instead middle-income countries and pharmaceutical companies face a patchwork of individual country-level negotiations over access to generics or pricing of branded drugs that do not necessarily correlate with actual public health needs or ability to pay.

**“...this is not a trade agreement. It’s about intellectual property and dispute settlement; the big beneficiaries are likely to be pharma companies...”**

— Paul Krugman, Princeton University professor  
2008 Nobel Prize winner in economics  
*New York Times* editorial, April 26, 2015

The proposed terms of the TPP will only exacerbate the difficulties that individual countries, the development community, and pharmaceutical companies face in improving access across middle-income countries. These countries are already struggling to pay for medicines and the situation will only worsen as newer drugs come out of the pipeline and are protected from generic competition.

### Conclusion

It is impossible to know the full ramifications of passing the TPP since even members of the U.S. Congress do not have access to all of the details or know what the final terms will be. Nevertheless, the history of IP provisions in previous FTAs has shown that they get progressively stronger and make access to medicines more difficult for those most in need. If in place a decade ago, the anticipated IP provisions of the TPP would have undermined the ability to develop the very HIV treatment programs that millions are dependent on today. Going forward, these terms will undermine these same treatment programs by making them more beholden to the good will of pharmaceutical companies rather than competitive market pressures facilitated by generic drugs and producers. The TPP’s movement toward stronger IP protections should be reversed to prevent unnecessary and harmful effects on global public health.

## References

- 1 Wikileaks (2014). Updated secret Trans-Pacific Partnership Agreement (TPP) – IP chapter (second publication). Available at <https://wikileaks.org/tpp-ip2/>
- 2 TRIPS Agreement, Article 33.
- 3 amfAR, The Foundation for AIDS Research (2015). Hepatitis C and drug pricing: the need for a better balance. Available at <http://www.amfar.org/HCV-Drug-Pricing/>
- 4 Wikileaks TPP Text, Article QQ.E.12 <https://wikileaks.org/tpp-ip2/tpp-ip2-chapter.pdf>
- 5 In general, new drugs are tested against placebos for safety and efficacy. Where the safety and effectiveness of a drug has already been established, it is unethical to perform new clinical trials that involve giving patients a placebo as doing so unnecessarily threatens their health and well-being. Likewise, trials that establish more effective dosing or superior tolerability of a drug over existing treatment are unethical if the new drug has already been established as a new standard of care. There are some circumstances, however, such as comparing a new drug against existing standards of care to test for “non-inferiority,” in which additional drug trials to develop safety and efficacy data may be ethically permissible.
- 6 Wikileaks TPP Text, Article QQ.E.16. Available at <https://wikileaks.org/tpp-ip2/tpp-ip2-chapter.pdf>
- 7 FDA (2015). Biosimilars. Available at <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/default.htm>
- 8 FDA. (2015). FDA approves first biosimilar product Zarxio. Available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm436648.htm>
- 9 Biologics Price Competition and Innovation Act (2009). Section 7002(k) (7)(A).
- 10 KEI Online (2013). TPP: Waxman letter to USTR opposing 12 year term of biologics exclusivity. Available at <http://keionline.org/node/1844>
- 11 Fiscal Year 2016 Budget of the U.S. Government. Available at <http://www.whitehouse.gov/sites/default/files/omb/budget/fy2016/assets/budget.pdf>
- 12 Wikileaks TPP Text, Article QQ.H.2. Available at <https://wikileaks.org/tpp-ip2/tpp-ip2-chapter.pdf>
- 13 Médecins Sans Frontières (2010). Victory for access to medicines as Valganciclovir patent is rejected in India. Available at <http://www.msfaccess.org/about-us/media-room/press-releases/victory-access-medicines-valganciclovir-patent-rejected-india>
- 14 Wikileaks TPP Text, Article QQ.E.1. Available at <https://wikileaks.org/tpp-ip2/tpp-ip2-chapter.pdf>
- 15 TRIPS Agreement, Article 27(3). Note, however, that the TRIPS agreement does require countries to either offer patents or develop a *sui generis* system for protection of plant varieties.
- 16 Wikileaks TPP Text, Article QQ.E.1. Available at <https://wikileaks.org/tpp-ip2/tpp-ip2-chapter.pdf>
- 17 Wikileaks TPP Text, Article QQ.E.1 Available at <https://wikileaks.org/tpp-ip2/tpp-ip2-chapter.pdf>
- 18 Wikileaks TPP Text. Available at <https://wikileaks.org/tpp-ip2/tpp-ip2-chapter.pdf>
- 19 Office of the U.S. Trade Representative. United States-Korea Free Trade Agreement. Available at: <https://ustr.gov/trade-agreements/free-trade-agreements/korus-fta/final-text>
- 20 Office of the U.S. Trade Representative. United States-Colombia Trade Promotion Agreement (TPA). Available at <https://ustr.gov/trade-agreements/free-trade-agreements/colombia-fta>
- 21 Office of the U.S. Trade Representative. United States-Panama Trade Promotion Agreement. Available at <https://ustr.gov/trade-agreements/free-trade-agreements/panama-tpa/final-text>
- 22 Office of the U.S. Trade Representative. United States-Peru Free Trade Agreement. Available at <https://ustr.gov/trade-agreements/free-trade-agreements/peru-tpa/final-text>
- 23 Office of the U.S. Trade Representative, Dominican Republic-Central America FTA. Available at <https://ustr.gov/trade-agreements/free-trade-agreements/cafta-dr-dominican-republic-central-america-fta/final-text>
- 24 Note, however, that the TRIPS agreement does require countries to either offer patents or develop a *sui generis* system for protection of plant varieties.
- 25 WHO Fact Sheet November 2014
- 26 Shaffer ER, Brenner JE (2009). A trade agreement's impact on access to generic drugs. *Health Aff (Millwood)*. 28(5): w957-w968.
- 27 KEI Online (2012). Who USTR clears to see secret text for IPR negotiations? (Such as TPPA) Available at <http://keionline.org/node/1362>
- 28 *The Washington Post* (December 13, 2014). Obama says he willing to defy Democrats on his support of Trans-Pacific Partnership. Available at [http://www.washingtonpost.com/politics/obama-says-he-willing-to-defy-democrats-on-his-support-of-trans-pacific-partnership/2014/12/03/25edcaf4-7b30-11e4-84d4-7c896b90abdc\\_story.html](http://www.washingtonpost.com/politics/obama-says-he-willing-to-defy-democrats-on-his-support-of-trans-pacific-partnership/2014/12/03/25edcaf4-7b30-11e4-84d4-7c896b90abdc_story.html)
- 29 *The Washington Post* (April 23, 2015). There may have been a poison pill in the fast-track trade bill. Available at <http://www.washingtonpost.com/blogs/wonkblog/wp/2015/04/23/there-may-have-been-a-poison-pill-in-the-fast-track-trade-legislation/>
- 30 *The New York Times* (April 21, 2015). Deal on trade pact gives Obama authority but builds in a delay. Available at [http://www.nytimes.com/2015/04/22/business/obama-fast-track-pacific-trade-deal.html?\\_r=0](http://www.nytimes.com/2015/04/22/business/obama-fast-track-pacific-trade-deal.html?_r=0)
- 31 Office of the U.S. Trade Representative. United States-Korea Free Trade Agreement. Available at <https://ustr.gov/trade-agreements/free-trade-agreements/korus-fta/final-text>
- 32 Wikileaks TPP Text. Available at <https://wikileaks.org/tpp/static/pdf/Wikileaks-secret-TPP-treaty-IP-chapter.pdf>
- 33 *Business Standard* (December 3, 2014). HIV affected protest as India hosts RCEP trade negotiations. Available at [http://www.business-standard.com/article/pti-stories/hiv-affected-protest-as-india-hosts-rcep-trade-negotiations-114120300806\\_1.html](http://www.business-standard.com/article/pti-stories/hiv-affected-protest-as-india-hosts-rcep-trade-negotiations-114120300806_1.html)
- 34 Regarding scope, the leaked TPP language includes a list of diseases for which TRIPS flexibilities are “particularly” allowed. While not formally restricted to these diseases, such language was expressly rejected during the Doha Declaration negotiations establishing the flexibilities as to not indirectly limit their scope. Re-inclusion in the TPP may have that effect.

# amfAR

MAKING AIDS HISTORY

amfAR, The Foundation for AIDS Research

[www.amfar.org](http://www.amfar.org)

Public Policy Office  
1150 17th Street, NW  
Suite 406  
Washington, DC 20036  
USA  
+1.202.331.8600