Comments for the Record to the Subcommittee on Trade of the Committee on Ways and Means

Hearing on the Trans-Pacific Partnership Agreement (TPPA)

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Introduction

The United States' proposed text on intellectual property for the Trans Pacific Partnership Agreement (TPPA) will harm people living in the United States and other TPPA member states. The lack of transparency in the negotiation is appalling and unequal, particularly where corporate interests have preferred legal access to information about the negotiations while providing information about the negotiation to the general public is illegal, and subject to career ending sanctions and the possibility of long prison terms.

USTR has proposed several measures that will clearly increase prices and restrict access to medicines. These proposals go beyond the requirements of the WTO Agreement on TRIPS, limit the applicability of the Doha Declaration on TRIPS and Public Health, and abandon the May 10th Agreement between the Bush Administration and the House of Representatives which agreed that certain TRIPS-plus mechanisms should not be part of a mandatory protocol, which places the Obama Administration closer to the pharmaceutical lobby than the Bush Administration, as regards trade policy

In addition, USTR's text contains multiple proposals that are inconsistent with current U.S. law. These areas would give greater privileges to owners of patents, copyrights and other intellectual property rights, undermining consumer rights and protections.

I. Transparency

The TPPA has been negotiated in secret and the proposed texts have not been officially released to the public. The negotiations are conducted behind closed doors and the general public is not permitted to view the texts. Transparency is a necessary for stakeholders to evaluate the proposals that will ultimately affect them and provide feedback. The secrecy of the negotiations denies the general public access to information and the opportunity to effectively engage in the democratic process.

The TPPA currently involves negotiations between nine countries—the United States, Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore and Vietnam—of diverse economies and resources. It is expected that the TPPA will be expanded to include an even larger group of countries; in fact, Japan, Canada and Mexico have already expressed interest in joining. The norms set by the TPPA could expand beyond these countries as well, to include numerous additional countries in Latin America and Asia. With a negotiation that will set norms of such magnitude, transparency is critical to ensuring that the general public is informed of the proposals that will affect them.

A. The US proposals should be released to the general public and USTR should invite comment on its proposed texts.

This lack of access to information has been intentionally unequal. Although the general public is routinely denied access, some corporate interests have had the opportunity to have "cleared advisors" and others view the texts, provide comments and influence the negotiations.

While it is true that some texts have been leaked, including several outlining the United States position on areas related to intellectual property and access to medicines or medical technologies, the public should not have to rely on leaks as a source of information. Furthermore, when these texts are made available through leaks, their unauthorized disclosure may be subject to government sanctions, including potential career ending consequences or imprisonment for persons leaking the documents. Leaks are therefore an infrequent and unreliable source and the public should not be forced to rely on information through this channel.

The refusal to release negotiating texts puts the public at a disadvantage because it is difficult and, at times, impossible to provide meaningful comments to USTR and other US agencies. The precise wording of the provisions, references to other documents and instruments, and cross-references throughout the text are vital in fully understanding the impacts of the agreement. Without access to the negotiating texts, the public's involvement and engagement in the process is hampered. Transparency is needed to legitimize the process of the negotiations and the US government should release its proposals and accept public comment.

B. The United States would greatly benefit from public comment on the proposed texts

A period for public comment on the proposed texts would enhance the agreements by allowing the United States to draw upon the expertise of academics and practitioners across diverse fields. These individuals and civil society organizations can offer their knowledge and specific expertise to improve the agreement.

C. Texts of agreements negotiated in other fora have been released

The secrecy of the TPPA negotiations is unnecessary and the texts of various other agreements were released to the public without harm to the negotiations. In multilateral fora such as the World Intellectual Property Organization (WIPO) and the World Health Organization (WHO), negotiating texts are widely distributed to the public, published on the website or reported in the minutes.

In another trade agreement for the Anti-Counterfeiting Trade Agreement (ACTA) to which the United States is a party, the negotiating texts were eventually made public after intense pressure to release the documents. The release of these documents did not cause negotiations to break down and, in fact, ACTA was eventually concluded and several countries signed the agreement—including the United States, Australia, Canada, Japan, Morocco, New Zealand, Singapore and South Korea—during a signing ceremony on October 1, 2011. Despite claims to the contrary, public release of negotiating texts did not stall the negotiations or eventual conclusion of the agreement.

The United States has, in fact, sought public comment on other agreements negotiated at the multilateral level. For example, in March 2011, WIPO created a "wiki" for its proposed treaty on traditional cultural expressions and posted the actual draft language to this site. WIPO invited the public to comment on each article. The day that comments were due on the "wiki," the US Patent and Trademark Office (USPTO) held a stakeholder meeting to discuss the drafted treaty language. A broad range of stakeholders attended to share their views on each article and the diverse expertise provided USPTO with the information necessary to strengthen the document.

By following these examples, the United States can legitimize the process of its negotiations and allow the public to engage in the democratic process.

II. Access to Medicines

One of the primary concerns of the intellectual property chapter text tabled by the U.S. on February 10, 2011 and in September 2011 includes the effect these norms will have on access to medicines. The U.S. proposal for the TPPA includes numerous provisions that go well beyond the TRIPS Agreement. TRIPS reflects international standards for protection of intellectual property and provisions that mandate stricter rules upsets the balance between rights for right holders and development or public health concerns. These proposals would erode existing public health safeguards and greatly endanger access to affordable medicines.

References to U.S. proposed TPPA text reflect the leaked copies of the text tabled in February[1] and September.[2]

1 http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf

2 http://www.citizenstrade.org/ctc/wp-content/uploads/2011/10/TransPacificIP1.pdf

A. Expanded scope of patentability

Article 8.1 and 8.2 of the text tabled by USTR in February 2011 broadly defines the scope of patentability beyond the requirements of TRIPS. It would make "new forms, uses or methods" patent eligible "even if such invention does not result in the enhancement of the known efficacy of that product" which would effectively extend monopoly power over existing products.

Article 8.2 would specifically require parties to make patents available for plants, animals, diagnostic, therapeutic and surgical methods which directly contradicts the exclusion provided for in Article 27.3 of TRIPS. Requiring patents on surgical methods not only raises serious ethical concerns but also draws into question the proposal's consistency with U.S. law which does not enforce patents against medical professionals.

Article 8.3 provides only a very narrow exclusion from patentability under the TPPA and creates an exhaustive list of what may be excluded, also going beyond the language of TRIPS. This expanded scope of patentability coupled with the limitations on exclusions creates a scenario where monopoly power is strengthened and extended over products, delaying entry of generic medicines into the market and raising costs.

B. Patent term extensions

USTR proposed text in September 2011 that would require parties to provide patent term extensions to compensate for "unreasonable delays" in the granting of a patent. According to the language of the U.S. proposal, patent term extensions would be mandatory and no exceptions are provided for, other than those delays attributable to the patent applicant. Patent term extensions are not required under TRIPS and serves only as a benefit to the patent-owner, extending the monopoly on life-saving medicines. Thus, it would delay entry of generic medicines, keeping costs out-of-reach for many patients in developing countries. The proposal would also likely put undue pressure on parties to grant patents, even absent a thorough examination, which could result in overpatenting of patent of poor quality.

Notably, this proposal represents a backtracking from the "May 10th" Agreement between the Bush Administration and Congress on May 10, 2007. Under the May 10th Agreement, patent term extensions were voluntary, rather than mandatory.

C. Exclusion of pre-grant opposition

Article 8.7 from the February 10, 2011 proposal would prohibit pre-grant opposition systems. Although pre-grant opposition can improve patent quality and reduce the granting of substandard patents, the U.S. would seek to eliminate these systems through its free trade agreements. Elimination of pre-grant opposition benefits pharmaceutical companies by increasing the cost of challenging patents and giving the right holder the presumption of patentability. Even where a patent challenge is successful, during the period between the grant of the patent and successful post-grant opposition, a period of monopoly will exist on a product that should never have been granted a patent.

D. Exclusive rights in test data

Article 9.2, proposed in September 2011, would provide for mandatory grant of exclusive rights in test data. The proposal goes beyond the requirements of TRIPS which requires for protection only on "undisclosed test or other data, the origination of which involves a considerable effort." Furthermore, countries only need to protect "against unfair commercial use." Although Article 39.3 of TRIPS requires parties to provide protection, it does not specify the mechanism for protection and does not require exclusive rights over test data.

The U.S. proposal could permit protection beyond "undisclosed information" and may also extend protection of data to more than just that which requires "considerable effort." The US proposal would provide for exclusive rights in test data, which has serious implications for medical ethics that prohibit the unnecessary duplication of clinical trials. This TRIPS-plus measure of creating a period of exclusive rights in test data make it costly, time consuming and typically impossible to register new medicines without duplicating clinical studies, even where the product is not protected by patents.

In addition to a mandatory five years of exclusive rights in test data, the U.S. proposal also provides for an additional three years of protection submitted for second indications or uses for a previously approved chemical entity. The three years of protection for second uses is particularly objection in the context of developing countries.

Our concerns about test data protection extend both to developing countries, which high prices have the most severe impact on access, and to the U.S. and other high income countries, where high prices for medicines also harm the public, as consumers and taxpayers.

The language of the TPPA proposal would limit legislative efforts to reform our system of protection in test data. In the 111th Congress, Senator Sanders introduced S.3921, the Ethical Pathway Act of 2010. This bill would eliminate exclusive rights in test data where repetition of the clinical trial would violate medical ethics. This Act seeks to ensure that applicants seeking regulatory approval for a pharmaceutical or biological product would not be forced to repeat clinical trials in violation of the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects. Instead, the Ethical Pathway Act of 2010 would institute a cost-sharing mechanism that would be TRIPS compliant but allow a fair and ethical method for generic entry while also compensating the originator of the test data.

E. Patent linkage

Article 9.5 of the USTR proposal would make patent linkage mandatory, a serious retreat from the May 10th Agreement where patent linkage was only optional. Patent linkage is a burdensome system for drug regulatory authorities because there are often very large numbers of patent families on a single medicine. These requirements could present particularly high costs for the authorities of less developed countries.

Patent linkage is another measure that goes beyond the requirement of TRIPS and can delay entry of generic medicines into the market. The May 10th Agreement recognized that patent linkage was more appropriate as a voluntary measure, rather than a mandatory obligation.

F. Access window

USTR claims that the provisions relating to patent term extensions, exclusive rights in test data and patent linkage are part of an access to medicines strategy because these rights are provided when the pharmaceutical company registers within an "access window." However, the "access window" merely provides stronger monopolies for right holders and will actually delay access to affordable medicines.

This window purportedly operates by allowing a party to require registration within a specified period of times (currently undefined and to be negotiated) in order to receive these benefits. However, it applies only for countries that use reference registration, which is reliance on evidence of prior registration in another country. Countries that do not use reference registration may not require applicants to register their drugs within the "access window" in order to receive the TRIPS-plus benefits of patent term extensions, exclusive rights in test data, and patent linkage. Thus, they will be forced to provide monopoly-enhancing rights regardless of when the drugs are registered.

Even for the countries that do use reference registration, application of the access window is merely voluntary whereas provisions for these three TRIPS-plus measures are mandatory. Furthermore, applicants registering their drugs need not complete the process for registration within the access window in order to qualify for patent term extensions, exclusive rights in test data and patent linkage. The U.S. proposal provides only that patent holders need to "commence the process of obtaining marketing approval" and that "while a Party may impose reasonable additional requirements or deadlines . . . satisfaction of those additional requirements or deadlines . . . shall be recognized by the Party as necessarily occurring after the commencement of the marketing approval." Under the U.S. proposal, a company does not need to complete the process within a specified time, but rather, the commencement is enough to satisfy the "access window" and receive the TRIPS-plus benefits.

This so-called access to medicines strategy will likely endanger lives by extending monopoly protections on live-saving medicines. It is more focused on market access than access to medicines and by making TRIPS-plus measures such as patent term extensions, exclusive rights in test data, and patent linkage mandatory requirements, the TPPA will delay entry of generic drugs into the market which keeps prices on medicines high and unaffordable for those in developing countries. It is quite unfortunate that the USTR has proposed these measures for the TPPA which represent a serious retreat from the public health balance agreed upon in the May 10th Agreement.

G. Doha declaration and measures to protect public health

The text relating to public health understandings and the Doha Declaration on the TRIPS Agreement and Public Health could be read as intent by USTR to limit the application of this Declaration to "cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency."[3] Although the Doha Declaration applies to all diseases, the limitations in this language could be seen as an effort to limit its application to a narrow handful of diseases and as excluding, for example, non-communicable diseases.

While USTR makes efforts to possibly limit the Doha Declaration, it should consider that compulsory licenses have been issued recently in the U.S. for medical treatments outside of "HIV/AIDS, tuberculosis, malaria" or cases of emergency. For example, compulsory licenses have been issued for contact lenses[4] as well as a device to treat aortic valve stenosis.[5]

The possible limitation of this text is highly concerning for access to medicines and any language that could serve to limit applicability of the Doha Declaration should be eliminated from the text.

III. Inconsistencies with United States Law

In addition to our serious concerns with respect to the negative impact the proposed text would have on access to medicines and the public health, we believe that the USTR inappropriately pushes norms that are inconsistent with current US law. US norms are often inappropriate in the contexts of developing countries; the proposals are even more inappropriate when they would introduce backdoor changes into our own laws or block current legislative reform efforts. Although we have highlighted some selected areas of concern with respect to inconsistencies between the USTR proposal for TPPA and current US law in these comments, additional examples and our analysis is available in our August 30, 2011 paper, *Inconsistencies Between the U.S. Proposal for the IP Chapter of the TPPA and U.S. law*,[6] which can be found at http://keionline.org/node/1306. Changes to our current laws and interpretations of our current laws are best left to the purview of our Legislative and Judiciary branches, respectively, and not to be negotiated behind closed doors by our Executive branch.

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3 Article [X].2 of the U.S. text tabled in September 2011.

4 http://keionline.org/node/1219

5 http://keionline.org/node/1218

6 Note that this paper was written prior to USTR's tabling of its "placeholder" text for several controversial areas that impact access to medicines, including those on patent term extensions, protection of regulatory test data, and patent linkage. These proposals, as noted in the preceding section, do not comport with the "May 10th Agreement."

A. Copyright

The USTR proposal would give copyright owners of books, journals, sheet music, sound recordings, computer program, and audio and visual works the exclusive rights over parallel importation. Although the U.S. Copyright Act grants numerous specific rights in copyrighted works, subject to limitations and exceptions, it is unsettled as to whether the right to prohibit parallel importation of lawfully acquired works exists.

B. Technological Protection Measures

USTR's proposal contains several provisions with regard to technological protection measures (TPM). While some of these provisions replicate current U.S. law, others go beyond our current requirements.

For example, Article 4.9(c) of the February 10, 2011 USTR draft explicitly provides that a violation of a TPM is a "separate cause of action, independent of any infringement that might occur under the Party's law on copyright and related rights." Thus, a person could be found liable for circumventing a TPM even where such conduct is considered to be legitimate and not an infringement of copyright, undermining the important and existing copyright limitations and exceptions under U.S. law. Whether an underlying infringement is required under the Digital Millennium Copyright Act (DMCA) to find a person guilty of circumventing a TPM is currently unsettled in the United States with the Courts of Appeals for the Federal Circuit and Ninth Circuit coming to opposite conclusions.

The provisions for civil remedies for circumvention of a TPM do not contain the same limitations and exceptions as provided for by the DMCA.[7] Under the DMCA, damages may be reduced or remitted for "innocent violations." The TPPA proposal, by contrast, envisions an exception only for nonprofit libraries, archives, educational institutions or public noncommercial broadcasters.

C. Injunctions

Depending on how Article 12.2 of the U.S. proposed February 2011 text is read, if parties are required to provide injunctions in all cases of infringement, then it is inconsistent with several current U.S. laws that eliminate injunctions even where infringement occurs. These examples extend to trademarks,[8] copyrights,[9] patents,[10] plant breeder rights,[11] designs,[12] or mask works fixed in a semiconductor chip product.[13]

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7 17 U.S.C. §1203(c)(5)

8 5 U.S.C. §1114 (innocent infringement by publishers)

9 17 U.S.C. §512 (limitations on liability relating to online material); 17 USC 907 (innocent infringement of semiconductor chip design) and 28 U.S.C. §1498(b) (use by or for the government)

10 35 U.S.C. §271(e)(3)(safe harbour exception for uses of patents related to development and submission of information concerning sale of drugs or veterinary biologic products); 35 U.S.C. §271(e)(6)(B)-(C) (non-disclosed biological product patents); 35 U.S.C. §272 (temporary presence in the United States, meeting obligations under Chicago and Paris Conventions); 35 U.S.C. §287 (limitation on damages and other remedies; no injunctions for patent infringement by medical practitioners); 42 U.S.C. §2184 (regarding nuclear energy); and 28 U.S.C. §1498(a) (use by or for the government).

D. Damages

USTR's proposal would likely increase damages beyond that which would be granted under current U.S. law in several instances. For example, under Article 12.3 of the USTR proposal, judicial authorities would be required to take into account the suggested retail price of an infringing product. Under current U.S. law, a reference to "suggested retail price" as consideration for damages appears only in reference to importation of goods bearing an infringing trademark under the Tariff Act of 1930. With respect to infringing copyrighted goods, U.S. law currently uses "actual damages" as the appropriate benchmark.[14] Similarly, under U.S. patent law, the phrase "damages adequate to compensate for the infringement" is used.[15]

Furthermore, the USTR proposal flips the presumption of the grant of attorney's fees and court costs. Article 12.5 of the February 10, 2011 proposal mandates court costs in patent, trademark and copyright fees as well as attorneys fees for copyright and trademark cases "except in exceptional circumstances." Under current U.S, trademark law, by contrast, these fees are only allowed in exceptional cases rather than in the majority of cases. Similarly, U.S. copyright law does not require the grant of court costs or attorneys fees, but rather, is merely a discretionary award.

E. Enforcement in the Digital Environment

In its proposed text, USTR defines "service provider" more expansively[16] than the DMCA. The expansive definition in the TPPA would impose greater liability for transmission of online material and does not make a distinction between an entity and an individual person, unlike the DMCA.

F. Current legislative reform efforts for orphan works.

As noted above, there are several concerns with regard to the implementation of the damages provisions. These concerns extend not only to current U.S. laws, but also to those areas in need of reform and under consideration by Congress.

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11 28 U.S.C. §1498(d)(use by or for the government)

12 28 U.S.C. §1498(e) (use by or for the government).

13 28 U.S.C. §1498(e) (use by or for the government).

14 17 U.S.C. §504(b).

15 35 U.S.C. §284.

16 Article 16.3(b)(xii) of the USTR February 10, 2011 draft text.

The U.S. proposal could eliminate the possibility of reforms for changes to U.S. law to address the problem of what is known as "orphan works," copyrighted works where it is difficult or impossible to locate the owner of the copyright. Congress has considered legislation that would expand access to these orphaned woks. Limitations on injunctions and damages are central to these proposals, but the U.S. proposal for the TPPA would create a system that would calculate high damages or provide for large statutory damages. In 2008, Marybeth Peters, Registrar of Copyrights noted in a statement before the House of Representatives noted that statutory damages may be an inappropriate calculation of damages for orphan works.[17] Similarly, the Library of Congress found that large monetary damages substantially deterred use of orphan works and "reasonable compensation" was a more appropriate measure of damages.[18]

The TPPA text, as proposed by USTR in February 2011, would be inconsistent with efforts to reform U.S. copyright law, such as the Shawn Bentley Orphan Works Act of 2008. Although the Shawn Bentley Orphan Works Act would not provide for court costs and attorneys fees in the cases of orphan works, under the TPPA, both may be permitted under Article 12.4 of the U.S. proposal. Damages may also be higher, as measured by suggested retail price, actual damages or statutory damages under the TPPA than would be under Congressional efforts to address orphan works.

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[17] Statement of Marybeth Peters, Registrar of Copyrights, before the Subcommittee on Courts, the Internet and Intellectual Property, Committee on the Judiciary, United States House of Representatives, 110th Cong., 2nd Sess., March 13, 2008, *The "Orphan Works" Problem and Proposed Legislation*, *available at*, http://www.copyright.gov/docs/registrar031308.html.

[18] Library of Congress, Report of the Register of Copyrights, *Report on Orphan Works* (Jan. 2006) at 12-13, *available at* http://www.copyright.gov/orphan/orphan-report-full.pdf.