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RE: Ways and Means Hearing on the Trans Pacific Partnership Agreement
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This submission is made on behalf of myself, an academic and Associate Director of the Program on Information Justice and Intellectual Property at American University Washington College of Law.

I write to submit comments on the ways in which the recently leaked USTR proposals for intellectual property and pharmaceutical chapters in the Trans Pacific Partnership Agreement (TPP) extend beyond current U.S. law and policy. These comments are derived from, and are explained more fully in, a recent report I wrote on leaked USTR proposals for the TPP, authored with Professor Brook Baker (Northeastern University School of Law), Margot Kaminski (Executive director of the Yale Information Society Project) and Jimmy Koo (PIJIP Fellow). The full report is available at:

http://infojustice.org/tpp-analysis-december2011

The TPP is the latest in a dangerous shift in US trade policy towards a practice of international law making to bind the US to standards not reflected in its current law and without adequate transparency or public process. As in the recently negotiated, but not yet ratified, Anti-Counterfeiting Trade Agreement, TPP is being negotiated under intense secrecy. USTR proposals for new binding international minimum standards for domestic legislation are being crafted with close direction from a small group of industry stakeholders out of sight from the broader public that will be affected by the norms. There is no announced plan to subject any of the TPP texts to public release or comment. By virtue of several recent leaks of the USTR proposals, however, the public now has greater access to the substantive provisions the USTR is seeking. From these leaks, it clear that the USTR is using this negotiation to attempt to bind the US to a series of legislative minimum standards that are not reflected in current US law. The TPP proposal also dramatically alters US trade

policy, in particular by abandoning the 2007 New Trade Deal negotiated by the Bush Administration and Congressional leaders.[1]

Our full report contains detailed section by section analysis of the U.S. proposal and its potential effects on the public interest in the U.S. and abroad. Here I summarize some of the reports most notable findings.

A. Conflicts with US Copyright Law

- The USTR TPP proposal, if adopted, would expand the scope of copyright beyond existing U.S. law. The proposal includes rights to "prohibit all reproduction . . . in any manner or form, permanent or temporary (including temporary storage in electronic form)." Section § 106(1) of the Copyright Act does not prohibit reproduction "in any form." It rather prohibits reproduction of the "copyrighted works in copies or phonorecords."[2] Nor does U.S. law include an extension to "temporary storage in electronic form." U.S. law requires that a copy be "fixed," meaning "sufficiently permanent or stable to permit it to be perceived, reproduced, or otherwise communicated for a period of more than transitory duration."[3] The DMCA recognizes a safe harbor for "system caching,"[4] which is not included in the U.S. TPP proposal. The distinctions are particularly important for enforcement of copyright on the internet. Lower courts in the U.S. have, for example, held that copyright does not extend to buffer copies on the internet.[5] The USTR proposal also would require each party to provide the exclusive right to prohibit the "making available to the public of their works in such a way that members of the public may access these works from a place and at a time individually chose by them." There is a circuit split on the issue of whether §106(3) of the U.S. Copyright Act includes a "making available" right absent actual transfer.[6]

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[1] New Trade Policy for America, House Committee on Ways and Means, [hereinafter New Trade Policy], *available at* http://waysandmeans.house.gov/media/pdf/NewTradePolicy.pdf. An extended summary of the New Trade Policy provisions on patents/IPRs and access to medicines can be found in Mac Dressler, *American Trade Politics in 2007: Building Bipartisan Compromise*, Policy Brief, Peterson Institute for International Economics 25-26 (May 2007) *available at* http://www.iie.com/publications/pb/pb07-5.pdf. The New Trade Deal was included in revisions to the U.S.-Peru Trade Promotion Agreement and U.S.-Colombia Free Trade Agreement IP Chapters. U.S.-Peru Trade Promotion Agreement, Chapter 16 Intellectual Property Rights (revised June 29, 2007) available athttp://www.ustr.gov/webfm_send/1031; U.S.-Colombia Free Trade Agreement, Chapter 16 Intellectual Property Rights, available at http://www.ustr.gov/webfm_send/1336. *See Public Citizen Media Alert: On Access to Medicines, Obama Trade Pact Proposal Appears Set to Undo Bush-Era Improvements*. Public Citizen, 13 September 2011.

[2] See Jodie Griffin, *Inconsistencies Between the Trans-Pacific Partnership (TPP) Agreement and US Law*, Public Knowledge, www.publicknowledge.org/files/TPP%20Analysis.pdf

[3] Copyright Act, 17 U.S.C. § 101 (defining that "[c]opies" are material objects, other than phonorecords, in which a work is fixed by any method now known or later developed, and from which the work can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device. The term "copies" includes the material object, other than a phonorecord, in which the work is first fixed.").

[4] Digital Millennium Copyright Act, 17 U.S.C. § 512(b) (1998).

[5] *See* Cartoon Network LP, LLLP v. CSC Holdings, Inc., 536 F.3d 121 (2d Cir. 2008) (holding that buffer copies are saved for 'more than transitory duration' and are therefore insufficient for a work to be 'fixed').

[6] Jodie Griffin, *Inconsistencies Between the Trans-Pacific Partnership (TPP) Agreement and US Law*, Public Knowledge, www.publicknowledge.org/files/TPP%20Analysis.pdf

- The USTR proposed TPP article 4.2 would create a new international legal requirement to provide copyright owners an exclusive right to block parallel trade of copyrighted works – meaning the importation of a copyrighted work from one country where the good is voluntarily placed on the market to another country where the same good at the same price is unavailable.[7] In recognition of the divergence of legitimate policies between countries, the WTO TRIPS agreement leaves countries free adopt domestic policies on parallel importation through their regimes of exhaustion of intellectual property rights.[8] The extension of copyrights to parallel trade is unsettled in current U.S. law. The issue was recently litigated in the Supreme Court in *Costco v. Omega*, but the split decision did not resolve whether copyrights prevent parallel importation in the U.S.[9]

- USTR's proposed TPP Art. 4.5 would create a new mandatory minimum copyright term.[10] The proposal would take the current U.S. law standard in Copyright Act §§ 302(a)-(b) and change it to a minimum level of protection, whereas U.S. law sets this term as the ceiling.[11] TPP Art. 4.5(b) also fails to incorporate the U.S. law presumption that after 95 years from first publication or 120 years after creation an author's death is presumed,[12] which can assist some works in entering the public domain.

B. DMCA+ Anti-circumvention Liability

- USTR's proposal would require the adoption of a highly controversial form of anti-circumvention liability that does not fully embrace the flexibilities and exceptions in current U.S. law. Whereas DMCA § 1201(a)(2)(C) prohibits products "marketed" for use in circumventing a technological protection measure,[13] TPP Art. 4.9(a)(ii)(A) extends to products that are "promoted, advertised" for this purpose. DMCA § 1201(a)(2)(A) extends only to products designed "for the purpose of circumventing," while the TPP 4.9(a)(ii)(C) extends to any product "for the purpose of enabling or facilitating the circumvention," a potentially broader standard.[14] This also goes

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[7] Art. 4.2 ("Each Party shall provide to authors, performers, and producers of phonograms the right to authorize or prohibit the importation into that Party's territory of copies of the work, performance, or phonogram made without authorization, or made outside that Party's territory with the authorization of the author, performer, or producer of the phonogram").

[8] TRIPS Art. 6 (providing that "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights").

[9] See Alberto Cerda, *USTR New Exclusive Right for Copyright Holders: Importation Provision in the Trans Pacific Partnership Agreement (TPPA)* (July 5, 2011) http://keionline.org/node/1176

[10] 17 U.S.C. § 302 (2002) (specifying the duration of copyright for works created on or after 1/1/78).

[11] See Jodie Griffin, *Inconsistencies Between the Trans-Pacific Partnership (TPP) Agreement and US Law*, Public Knowledge, www.publicknowledge.org/files/TPP%20Analysis.pdf

[12] 17 U.S.C. § 302(e) ("After a period of 95 years from the year of first publication of a work, or a period of 120 years from the year of its creation, whichever expires first, any person who obtains from the Copyright Office a certified report that the records . . . disclose nothing to indicate that the author of the work is living, or died less than 70 years before, is entitled to the benefit of a presumption that the author has been dead for at least 70 years.").

[13] 17 U.S.C. § 1201(a)(2)(C) (prohibiting product, service, device, component, or part thereof that "is marketed by that person or another acting in concert with that person with that person's knowledge for use in circumventing a technological measure that effectively controls access to a work protected under this title.").

[14] Jodie Griffin, *Inconsistencies Between the Trans-Pacific Partnership (TPP) Agreement and US Law*, Public Knowledge, www.publicknowledge.org/files/TPP%20Analysis.pdf

beyond ACTA Art. 27.6(a)(ii).[15] Art. 4.9(a), by virtue of the requirement to include "the remedies and authorities listed in subparagraphs (a), (b), and (f) of Article [15.5] as applicable to infringements," requires "the imposition of actual terms of imprisonment when criminal infringement is undertaken for commercial advantage or private financial gain." This is inconsistent with 17 U.S.C. § 1204, which permits fines or imprisonment for violations of anti-circumvention standards.[16]

C. *Expansion of Rights Management Protection*

- The USTR proposal on protection of rights management information goes beyond current U.S. law. Current U.S. law only prohibits the distribution, importation or public performance of works knowing that rights management information has been removed or altered.[17] The TPP proposal also prohibits a person from broadcasting, communicating, or making available the work to the public.[18] It is noteworthy that the "making available" standard is in other U.S. free trade agreements and in the WIPO copyright treaties, but is not reflected in U.S. law. The definition of "rights management information" in TPP proposed Art. 4.10(c) is similar to that in the DMCA, except it specifically omits the exception for "public performances of works by radio and television broadcast stations" in DMCA §§ 1202(c)(4),(5).[19]

D. *Conflicts with International Standards on Internet Domain Names*

- The USTR TPP proposal includes provisions on internet domain names that would preempt expert discussions on this very topic in ICANN's multi-stakeholder forum. The proposal is also counter to existing ICAAN Principles for the Delegation and Administration of ccTLDs, which "should recognise that ultimate public policy authority over the relevant ccTLD rests with the relevant government or public authority."[20] The WSIS Tunis Agenda for the Information Society – agreed upon by the UN-sponsored World Summit on the Information Society in 2005 – similarly states that "Countries should not be involved in decisions regarding another country's country-code Top-Level Domain (ccTLD). Their legitimate interests, as expressed and defined by each country, in diverse ways, regarding decisions affecting

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[15] ACTA Art. 27.6(a)(ii) (prohibiting "the offering to the public by marketing of a device or product, including computer programs, or a service, as a means of circumventing an effective technological measure.").
[16] Jodie Griffin, *Inconsistencies Between the Trans-Pacific Partnership (TPP) Agreement and US Law*, Public Knowledge, www.publicknowledge.org/files/TPP%20Analysis.pdf
[17] 17 U.S.C. § 1202(b)(3) ("distribute, import for distribution, or publicly perform works, copies of works, or phonorecords, knowing that copyright management information has been removed or altered without authority of the copyright owner or the law.").
[18] See Jodie Griffin, *Inconsistencies Between the Trans-Pacific Partnership (TPP) Agreement and US Law,* Public Knowledge, www.publicknowledge.org/files/TPP%20Analysis.pdf
[19] 17 U.S.C. §§ 1202(c)(4), (5) ("(4) With the exception of public performances of works by radio and television broadcast stations, the name of, and other identifying information about, a performer whose performance is fixed in a work other than an audiovisual work. (5) With the exception of public performances of works by radio and television broadcast stations, in the case of an audiovisual work, the name of, and other identifying information about, a writer, performer, or director who is credited in the audiovisual work."). See Jodie Griffin, *Inconsistencies Between the Trans-Pacific Partnership (TPP) Agreement and US Law,* Public Knowledge, www.publicknowledge.org/files/TPP%20Analysis.pdf
[20] Principles for Delegation and Administration of ccTLDs, Presented by Governmental Advisory Committee. 23 February 2000. Available at http://www.icann.org/en/committees/gac/gac-cctldprinciples-23feb00.htm

their ccTLDs, need to be respected, upheld and addressed via a flexible and improved framework and mechanisms."[21]

E. Abandoning the 2007 New Trade Policy on Access to Medicines

- The USTR proposal would abandon the access to medicines flexibilities of the 2007 New Trade Deal and the U.S.-Peru Free Trade Agreement. The general rule under the TPP proposal would be that members must grant patent extension for regulatory delays, "data exclusivity" registration monopolies that would extend to unpatented drugs, and patent/registration linkage that would require registration entities to enforce patent rights. All of these requirements were made optional or restricted in scope in the 2007 deal. The U.S. Access Window provides countries with the option of having marketing approval procedures that rely in whole or in part on the fact of marketing approval/registration in another country. If countries have such a fast-track, reliance mechanism, they can limit patent term extensions related to regulatory delays (not patenting delays), data protection, and patent/registration linkage for applicants who use the reliance mechanism within an unspecified number of years – the "access window." Ultimately, these provisions heighten protections and opportunities for brand name drug suppliers while limiting market access for more affordable generic products in poor countries. They are a significant step back in U.S. policy promoting access to affordable medicines in developing countries.

- Further threatening access to medicines, the TPP proposal would dramatically alter the international obligations on some of the poorest countries in the world to grant patent monopolies on needed health technologies, including by granting patents on news forms or uses of unpatented technologies, even if the modification "does not result in the enhancement of the known efficacy of that product." Each new patent on new forms, uses, or formulation of an existing medical product will result in a new 20-year patent running from the date of patent application, thereby "evergreening" monopoly rights on the underlying medical product.[22] In direct contradiction to TRIPS Art. 27.3, TPP Art. 8.2 would require that "each party shall make patents available for . . . (a) plants and animals, and; (b) diagnostic, therapeutic, and surgical methods for the treatment of humans or animals." TPP art. 8.7 contains TRIPS-plus restrictions on the grounds for patent revocation and on processes for permitting pre-grant opposition of patent applications. These provisions will predictably lead to higher prices and lower availability of pharmaceutical products, especially in developing countries.

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[21] Tunis Agenda for the Information Society, WSIS-05/TUNIS/DOC/6(Rev. 1)-E. 18 November 2005. Available at: http://www.itu.int/wsis/docs2/tunis/off/6rev1.html

[22] For example, since the filing of the original patent application on ritonavir in 1980 there have been over 800 families of ever-greening patent applications, most first filed in the U.S. Those patent applications filed in 2009 will extend exclusivity period from the original 2000 date to 2029 – twenty-nine extra years and counting. *See* World Intellectual Property Organization, PATENT LANDSCAPE REPORT ON RITONAVIR (2011), *available at* http://www.wipo.int/export/sites/www/patentscope/en/programs/patent_landscapes/reports/documents/ritonavir_plr_08112011_with_old_cover.pdf. Note, some of the ritonavir patents filed are process rather than product patents.

F. Threatening Medicaid through Restrictions on Pharmaceutical Reimbursement

- Finally, the TPP proposal would export a new and controversial set of restrictions on the efficacy of price negotiations in pharmaceutical reimbursement programs that have never before been proposed for developing countries and that are not adhered to in the U.S. itself. The chapter advances proposals that would undermine countries' policy space to adopt and enforce therapeutic formularies, reimbursement policies and other price moderating mechanisms within public health systems. The U.S. succeeded in obtaining similar chapters in trade agreements with Australia and Korea, two OECD countries. These standards are inappropriate for developing countries. The substantive provisions in the proposal (and included in the Australia and Korea agreements) are not followed by U.S. pharmaceutical reimbursement programs, most notably Medicaid. And unlike the proposals in Australia and Korea, the TPP proposal does not contain a clear carve out of US programs. Indeed, other countries have indicated that they will insist on application of the chapter to Medicaid and other US programs if the US insists on including it in the agreement. The heart of the proposal would require that countries establish new administrative and judicial appeal systems to contest whether public drug reimbursement rates "appropriately recognize the value" of pharmaceutical patents. Medicaid programs, which use the same kinds of formularies as foreign drug purchasing programs, do not provide such appeals and state officials have repeatedly testified to USTR and to Congress that such provisions would hamper the ability of public reimbursement programs to secure the lowest possible prices for public expenditures. The TPP chapter may be best seen as a significant step toward the pharmaceutical industry's ultimate goal, which is a binding international agreement on drug pricing that would restrain the ability of governments to use collective purchasing power to demand prices below "market" levels.[23] This is a radical proposal that is a completely inappropriate subject for closed door trade negotiations.

The upshot is that if the USTR succeeds in binding the US to these bold proposals, it will force Congress to change existing US law or risk the country being in breach of international law. This untoward state of affairs raises the acute risks of allowing international legislative minimum standards agreements to be negotiated behind closed doors. Unlike in a traditional legislative process, there is no opportunity for many key stakeholders to see and influence the policymaking in the TPP until the agreement is done. Closed-door international trade agreements are not the right vehicle for the alteration of US legislative policy. No country, including the U.S., has an interest in ceding this much policy flexibility to an international agreement, particularly through an international agreement subject to such a limited public process.

Congress may consider legislative and oversight functions that would ameliorate the lack of public process in the TPP negotiations. It could, for example, pass legislation requiring USTR to hold public notice and comment proceedings on USTR legislative minimum standard proposals before they are offered in international closed door negotiations. At minimum, Congress could hold hearings on the leaked proposals that are now publicly available to ascertain the range of interests affected by them.

[23] http://media.pfizer.com/files/news/kindler_testimony_sfc_071508.pdf