Response of Knowledge Ecology International to
Federal Register Notice, Docket ID USTR-2012-0014, Public Hearings:
Mexico Participation in Trans-Pacific Partnership Trade Agreement; Negotiating Objectives

Submitted by
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Introduction

Knowledge Ecology International (KEI) is a not-for-profit, non-governmental organization that searches for better outcomes, including new solutions, to the management of knowledge resources, particularly in the human rights and social justice context.

KEI files these comments in response to Federal Register Notices, Docket ID USTR-2012-0014, Public Hearings: Mexico Participation in Trans-Pacific Partnership Agreement; Negotiating Objectives. These comments are primarily related to item (h) "Relevant trade-related intellectual property rights issues that should be addressed in the negotiations." We also submit comments responding to USTR's call for "new approaches designed to promote innovation and competitiveness, encourage new technologies and emerging economic sectors."

In addition to the views expressed below, we incorporate by reference our previous comments and submissions made to U.S. government agencies. Specific reference to previous comments are included in the applicable sections below. More generally, we also draw your attention to KEI Comments on Inconsistencies Between the U.S. Proposal for the IP Chapter of the TPPA and U.S. law, available at http://keionline.org/sites/default/files/TPPA_USplus_30Aug2011.pdf. Additionally, there are relevant notes previously submitted by KEI in response to Federal Register Notice, Vol. 76, No. 235: 76480-76481 on Canada's Expression of Interest in the Trans-Pacific Partnership Trade Negotiations, submitted on January 10, 2012 and available here: http://keionline.org/sites/default/files/Federal_register_TPPA_Canada_10Jan2012.pdf

Transparency

From the outset, we note our continued objections to the secrecy surrounding the negotiations. A free trade agreement of this size—with the additions of Canada and Mexico, the number of parties to the TPPA now reaches eleven, with continued expansion throughout the APEC region expected—should be open and transparent. The public should not be kept in the dark regarding the negotiating positions of such a comprehensive agreement with a large trading area.

We are appalled by the lack of access to information for the general public, particularly in light of the inequalities of access between the public and corporate interests. Hundreds of corporations and special interests are afforded access to the negotiating texts, can comment on the negotiating positions and

effectively shape U.S. positions through the "cleared advisor" process of the trade advisory committees. Meanwhile, the general public is denied access to the same information, despite the impacts these policies will have on domestic law.

Not only has the general public been denied access to the negotiating texts, but staffers of members of Congress have similarly been prevented from viewing such texts even after receiving appropriate security clearances. Members of Congress themselves have reportedly been denied positions on the U.S. delegation at negotiating rounds and have been prevented from viewing the texts in convenient manners or sharing the texts with their staff members. Thus, the most well-informed population with regard to the TPPA are the corporate interests represented on the trade advisory committees.

Although USTR has claimed to make the TPPA negotiations transparent, without access to the actual texts, informed participation and commentary is extremely difficult. We note also that negotiations for large scale agreements in other for a have been much more transparent than the process has been for TPPA. For example, at WIPO, negotiations for an instrument on limitations and exceptions for persons who are visually impaired or have other disabilities have included the publication of several draft texts which include country negotiating positions and permit commentary from the public.

Enhancing transparency will legitimize the process. Public participation and engagement are critical to the democratic process, which has been severely curtailed in the TPPA. We recommend that USTR implement the recommendations submitted to USTR in 2009 by a group of public interest, consumer and public health organizations regarding transparency in free trade agreements. These recommendations can be found at http://keionline.org/content/view/246/1

We note also our opposition to the fact that Mexico and Canada, nearly a year after expressing formal interest in joining the TPPA, is still excluded from the negotiating room and do not have access to the negotiating texts. Even after formally being invited to join negotiations by the U.S., Mexico and Canada were excluded from the following two negotiating rounds held in San Diego, CA and Leesburg, VA, respectively. Should additional countries be invited to join the TPPA, we recommend their immediate access and participation in the negotiations.

Copyright

With respect to the copyright provisions, we incorporate by reference the letter we sent to Chief Negotiator, Barbara Weisel, on June 26, 2012. This letter, available at http://keionline.org/sites/default/files/TPP_Copyright_KEI2Weisel_26june2012.pdf, details many of our concerns regarding the U.S. copyright proposals including, among others, a ban on temporary reproductions, ban on parallel importation of copyrighted goods, lengthening copyright terms beyond the requirements of the Agreement on TRIPS, creating a separate cause of action for circumvention of a technological protection measure apart from any underlying copyright violation, and limitations and exceptions.

Limitations and Exceptions

In addition to the comments contained in the June 26, 2012 letter, we have additional concerns with respect to limitations and exceptions. During the thirteenth round of negotiations which took place in

San Diego, CA in July 2012, USTR tabled text on copyright limitations and exceptions. USTR issued a press release touting the new provision.

However, a leak of the text of the proposal reveals numerous problems and the text could actually hinder, rather than promote, a balanced copyright system with robust limitations and exceptions. The language tabled by the US would restrict limitations and exceptions to copyright by requiring all limitations and exceptions to comply with what is known as the "three-step" test, potentially endangering the fair use exceptions currently enjoyed in the U.S.

However, we note that under existing international jurisprudence, not all limitations and exceptions must comply with the three-step test; other specific limitations and exceptions exist under international agreements such as the Berne Convention, Agreement on TRIPS, the Rome Convention and others that fall outside the three-step test. The Berne Convention, for example, includes the following specific limitations and exceptions:

- Article 2(4)—Official texts of legislative, administrative and legal nature, and to official translations of such texts
- Article 2(8)—News of the day or miscellaneous facts having the character of mere items of press information
- Article 2bis(1)—Political speeches and speeches delivered in the course of legal proceedings
- Article 2bis(2)—Lectures, addresses and other works of this nature delivered to the public may be reproduced by press, broadcast, communicated to the public by wire and made subject of public communication when the use is justified by the informatory purpose
- Article 10—Quotations or uses for illustration or teaching, provided it is compatible with fair practice and the use does not exceed that justified by the purpose
- Article 10bis—reproduction by the press or broadcasting on current economic, political or religious topics or current events
- Article 13(1)—Compulsory licenses of sound recordings
- Appendix to the Berne Convention

Similarly, exceptions also exist under the Rome Convention and Agreement on TRIPS that are not required to comply with the three-step test.

According to leaked text, the U.S. has introduced the following language:

1. [US/AU: With respect to this Article [(Article 4 on copyright) and Article 5 and 6 (which deal with copyright and related right section)], each Party shall confine limitations or exceptions to exclusive rights to certain special cases that do not conflict with a normal exploitation of the work, performance, or phonogram, and do not unreasonably prejudice the legitimate interests of the right holder.]

2. Subject to and consistent with paragraph (1), each Party shall seek to achieve an appropriate balance in providing limitations or exceptions, including those for the digital environment, giving due consideration to legitimate purposes such as, but not limited to, criticism, comment, news reporting, teaching, scholarship and research.92

92 [US: For purposes of greater clarity, a use that has commercial aspects may in appropriate circumstances be considered to have a legitimate purpose under paragraph 2]

Here, the U.S. not only uses restrictive language ("shall confine"), but then goes on to list a number of areas that traditionally fall outside the three-step test, such as commentary, news reporting or teaching. The US language is therefore more restrictive than what is permitted under international agreements and places the exceptions currently relied upon under U.S. copyright law at risk.

As in other areas, the U.S. should not seek to introduce backdoor changes into U.S. law through the TPP, particularly when such changes would harm the public interest and important human and civil rights. The U.S. should support a flexible system, permitting countries to determine the appropriate limitations and exceptions under its own domestic laws in accordance with existing international agreements to which they may be a party, rather than imposing a more rigid standard that does not even comport with current domestic law or international standards.

Furthermore, contrary to the USTR press release, the U.S. proposal does little to actually mandate limitations and exceptions or provide balance in copyright. In addition to the restrictive nature of the proposal ("shall confine"), the language proposed merely mandates that parties "seek to achieve" a balance. Using the word "seek" does not obligate parties to actually implement balance and the U.S. proposal is thus insufficient and highly restrictive.

Patents and Public Health

KEI has previously submitted numerous comments with regard to patents and public health concerns. In addition to the specific comments detailed below, we incorporate by reference the comments made in the following documents: 1) Human rights complaint submitted to UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of health, available at http://keionline.org/sites/default/files/r2h_anand_grover_tpp_22march2011.pdf and 2) Civil Society Comments on the Trans-Pacific Partnership Agreement, available at http://keionline.org/sites/default/files/TPPApunchlist_18may2011.pdf.

Diagnostic, Therapeutic and Surgical Methods

The leaked text of the U.S. proposal from February 2011 would require parties to the TPPA to provide patents for "diagnostic, therapeutic and surgical methods for the treatment of humans or animals." Although TRIPS explicitly permits member states to exclude these categories from patentability, the US seeks to make mandatory patents for diagnostic, therapeutic and surgical methods. Requiring patents for diagnostic, therapeutic and surgical methods can create ethical issues for treating physicians. For example, a surgeon should be able to provide the best available surgical methods to a patient on the operating table without having to worry about potential liability for patent infringement. In fact, after lawsuits were filed against surgeons, the American Medical Association successfully lobbied Congress to provide an exclusion from enforcement.[1] Codified at 35 U.S.C. §287, the exclusion provides that patents are not enforceable against medical practitioners performing a medical

1 We note also that other associations have opposed patenting of surgical methods. For example, the American Academy of Orthopaedic Surgeons noted that, "Consistent with the Principles and Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, the American Academy of Orthopaedic Surgeons believes that it is unethical for orthopaedic surgeons to seek, secure, or enforce patents on medical or surgical procedures."

or surgical procedure. A corresponding exclusion does not appear in the leaked text proposed by USTR, potentially opening surgeons and medical professionals to liability for performing patented surgical methods on patients.

The North American Free Trade Agreement (NAFTA), an agreement between the U.S., Canada and Mexico provided an explicit carve out, replicating the exclusion permitted by TRIPS. Article 1709(3) of NAFTA explicitly states that, "A Party may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals." A contrary provision, such as the one the U.S. proposed in February 2011 for the TPPA, would negate this important exclusion contained in NAFTA.

We note that not only did NAFTA provide an exclusion from patentability for surgical methods, but the other FTAs signed by the US have all either provided for a similar provision or remained silent on the issue. In other words, this would be the first U.S. FTA to require parties to provide patents for diagnostic, therapeutic and surgical methods. We strongly oppose the inclusion of a requirement that parties make patents available for "diagnostic, therapeutic and surgical methods."

"TEAM" Approach

In the round of negotiations in September 2011 which took place in Chicago, IL, USTR tabled text covering issues such as patent term extensions, patent linkage and exclusive rights over test data which it labeled its "TEAM" approach. USTR issued a press release and white paper claiming that this proposal would promote access to medicines and protect public health. A leak of USTR's proposals, however, demonstrate concern for market access rather than access to medicines and we strongly oppose the retreat by USTR from the "New Trade Policy," also known as the "May 10, 2007 Agreement" between President George W. Bush and the then-Democratically controlled House of Representatives.

Although the May 10th Agreement made patent term extensions and patent linkage optional rather than mandatory, USTR's "TEAM" proposal backtracks from this policy and re-institutes mandatory extensions and linkage. Draft Article 8.6(b)-(c) provides that parties "shall" provide for patent term extensions while Article 9.5 of the U.S. proposal would require patent linkage. We note that patent term extensions and linkage are not required under TRIPS. Additionally, the USTR proposal mandates exclusive rights over test data but does not include any specific exception to override these exclusive rights in cases where a compulsory license has been issued as was recommended by the May 10th Agreement. While the May 10th Agreement was not a perfect solution to improving access to medicine, that approach provided additional flexibilities not contained in the "TEAM" approach.

USTR has claimed that by tying the TRIPS-plus measures patent term extensions, patent linkage and exclusive rights over test data to a so-called "access window" where companies would only get these benefits if they registered their products within a certain period of time, a closer look at the actual language of the proposal demonstrates that application of the window is very limited. The proposal appears to apply only to cases of registration by reference or prior approval in another party; countries that do not use reference registration systems cannot avail themselves of the "access window" and must provide these TRIPS-plus benefits even if a company does not register within a certain period of time. Additionally, according to Article 9.8 of the U.S. proposal, companies never have to complete the process of registration and permits companies to engage in delay tactics while taking advantage of the

"access window" where it has been implemented. The "access window" thus provides very narrow benefits to access to medicines, if at all, and is open to abusive practices by pharmaceutical companies which can avail themselves of the benefits of patent term extensions, patent linkage and exclusive rights over test data without actually promoting access to medicines.

In evaluating mechanisms to improve access to medicines, USTR must be cognizant of the pricing of treatments. Access to medicines does not merely refer to market access for pharmaceutical companies, but depends on the availability of generic competition which drives down prices for these important, life-saving drugs.

New Approaches

The Federal Register notice also seeks comments on "new approaches designed to promote innovation and competitiveness, encourage new technologies and emerging economic sectors." We note that numerous proposals have been made in the U.S. Congress that would achieve these very purposes and we encourage USTR to ensure that the TPPA text leaves flexibility to enact such new approaches, many of which would improve human rights, including access to medicines, or promote better ethical standards.

Cost-sharing mechanisms for clinical trial data

For example, on August 2, 2012, Senator Sanders (I-VT) introduced bill S.3506, the Ethical Pathway Act of 2012. This bill, based on an earlier bill introduced by then-Representative Sanders in 2007, seeks to "eliminate requirements to undertake duplicative clinical testing of new pharmaceutical drugs, vaccines, biological products, or medical devices, when such duplication is inconsistent with relevant ethical norms." Essentially, the bill seeks to institute cost-sharing mechanisms rather than exclusive rights over clinical test data. Exclusive rights over test data cause a number of known problems, creating additional barriers to entry of generic products, a waste of resources duplicating costly tests, and strong ethical concerns. Paragraph 20 of the Declaration of Helsinki covering Ethical Principles for Medical Research Involving Human Subjects provides, "Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results." Requiring duplication of clinical trials clearly violates this principle. The WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property cited the Declaration of Helsinki in calling for ethical principles for clinical trials.

The bill would provide that the originator of the clinical trial would be entitled to some compensation for its costs, but could not exclude others from relying on that data. This bill complies with TRIPS which requires only the protection of certain data, and does not require exclusive rights. Furthermore, this approach has found support in other FTAs involving high-income countries with respect to exclusive rights over test data for agricultural chemical products where the subject of testing involves animals. For example Article 6.11(3) of the EFTA-Colombia FTA, Article 6.11(3) of the EFTA-Peru FTA, and Annex XIII, Article 3 of the EFTA-Korea FTA all provide for cost-sharing models. Similarly, Article 11(7)-11(11) of the negotiations between Canada and the EU reveal an effort to avoid duplicative testing on vertebrate animals. We believe that these efforts to protect duplicative testing on vertebrate animals should be extended to protect human beings who would otherwise be the subject of duplicative testing on important medicines.

The leaked text of the U.S. proposal shows an effort by USTR to mandate exclusive rights over test data of five years, plus an additional three years for new indications, and placeholder text for the length of exclusivity for biologics. Including this language in the TPPA not only requires parties to enact laws contrary to ethical standards, but would lock-in the US and prevent legislative reform in this area.

We also have concerns regarding reports that the U.S. will table a period of exclusivity of twelve years for biologics. We note that President Obama's budget has recommended a period of seven years of exclusivity and that in 2009, the Federal Trade Commission has recommended a period of zero years. If reports are true that USTR will table twelve years of exclusive rights over test data for biologics, this proposal would run afoul of the President's proposed budget as well as recommendations by the FTC. We are strongly opposed to the inclusion of provisions mandating exclusive rights over test data, but also explicit periods of years for exclusive right that go beyond what is appropriate.

De-linkage

Another approach to promoting innovation involves de-linking the markets for products from the markets for innovation. The U.S. should encourage such efforts which help to promote innovation through incentives other than exclusive rights, such as cash prizes, while simultaneously permitting generic competition to reduce prohibitively high prices on life-saving medicines.

In 2011, Senator Sanders introduced two bills, S.1137 and S.1138, which would employ the de-linkage strategy and replace monopolies over pharmaceutical medicines with cash prizes. While S.1137 would apply to all pharmaceuticals, the focus of S.1138 is on HIV/AIDS. The Senate Committee on Health, Education, Labor and Pensions (HELP), Subcommittee on Primary Health and Aging held a hearing on S.1138. Notable witnesses included, among others, Nobel Prize winner in Economics, Joseph Stiglitz, and founder of the Creative Commons, Lawrence Lessig. Written and oral testimony from that hearing are available here: http://www.help.senate.gov/hearings/hearing/?id=2d5dda75-5056-9502-5d1a-2a40d8a92d51

The Executive Branch has also explored de-linkage models. In 2010, for example, Jeffrey D. Zients, Deputy Director for Management for OMB, published a "Memorandum For the Heads of Executive Department Agencies: Guidance on the Use of Challenges and Prizes to Promote Open Government."

In addition to the interest domestically in de-linkage mechanisms, internationally these alternatives have also garnered support. The World Health Assembly in May 2008 issued resolution 61.21, a "Global strategy and plan of action on public health, innovation and intellectual property." This document called for proposals "for health-needs driven research and development that include exploring a range of incentive mechanisms, including where appropriate, addressing the de-linkage of the costs of research and development and the price of health products and methods for tailoring the optimal mix of incentives to a particular condition or product with the objective of addressing diseases that disproportionately affect developing countries."

More recently, at the 65th World Health Assembly in May 2012, the WHA addressed the Report of the WHO's Consultative Expert Working Group (CEWG), which included recommendations that the WHO begin negotiations on a binding convention on the financing of research and development, and that such financing be tied to open knowledge approach and de-linkage of research and development costs

from product prices. Regional consultations are now taking place with respect to the CEWG report and implementation of the global strategy and plan of action.

We urge USTR to adopt flexible measures in the TPPA that preserve flexibilities under international agreements such as TRIPS. We also encourage USTR to be cognizant of new mechanisms to promote innovation, research and development, particularly when new methods such as those discussed above simultaneously provide incentives to develop while promoting high standards of ethics and accessibility.