

KEI statement on TPP for the January 13, 2016 hearing of the

UNITED STATES INTERNATIONAL TRADE COMMISSION

Investigation No. TPA-105-001

Trans-Pacific Partnership Agreement: Likely Impact on the U.S. Economy and on Specific Industry Sectors

Submitted on December 29, 2015

The following comment constitutes the Knowledge Ecology International (KEI) written statement prepared for the January 13, 2016 hearing on Investigation no. TPA-105-001, regarding the likely impact of the Trans-Pacific Partnership Agreement on the US economy.

KEI is a non-profit organization that searches for better outcomes, including new solutions, to the management of knowledge resources. KEI is focused on social justice, particularly for the most vulnerable populations, including low-income persons and marginalized groups. More about KEI is available from our website at: <http://www.keionline.org>.

KEI has testified before the USITC on two other occasions, including on November 17, 2015, on the "Economic Impact of Trade Agreements Implemented Under Trade Authorities Procedure,"¹ and on February 14, 2014, for the USITC investigation into Trade, Investment and Industrial Policies in India.² KEI references both of these earlier statements for this proceeding, including, for example, the discussion of the U.S. experience of compulsory licensing of patents provided to the USITC for the 2014 investigation of India, and the discussions of employment in intellectual property intensive industries in the November 17, 2015 testimony.

Our testimony today will address the following points.

1. High drug prices do not benefit the United States

There is an assumption, held by USTR, that high drug prices are a net benefit to the United States, associated with high paid jobs in the biomedical research and development area, where the United States has a competitive advantage. Many of the provisions in the TPP that were proposed and obtained by the United States are designed to increase drug prices, and/or lock-in policies that are associated with high drug prices. These include patent term extensions, low standards for granting drug patents, *sui generis* protections of test data used to register new drugs or expand their approved uses, high damages for patent infringement, and measures to

¹ Testimony of James Love, Knowledge Ecology International, United States International Trade Commission (USITC) hearing on "Economic Impact of Trade Agreements Implemented Under Trade Authorities Procedure", 2016 Report. Inv. No.: 332555 November 17, 2015.

² Testimony of James Love, Knowledge Ecology International, United States International Trade Commission (USITC) hearing on "Economic Impact of Trade Agreements Implemented Under Trade Authorities Procedure", 2016 Report. Inv. No.: 332555 November 17, 2015.

undermine national cost control efforts associated with reimbursements of drugs and medical devices.

Many of the intellectual property and reimbursement policies targeted by the TPP will have their greatest impact in lower income countries, including those countries considering joining the TPP later, where measures like patent term extensions, exclusive rights in test data or patents on new uses of older drugs are not already in place. But the TPP provisions also make it more difficult to implement cost control reforms in the United States and by introducing Investor State Dispute Settlement (ISDS) arbitration, create all sorts of new risks when drug or device manufacturers do not get what they want.

As discussed in the November 17, 2015 hearing, there are reasons to be concerned about any agreement that contributes to higher drug prices. The United States is facing its own crisis over the affordability of drugs, including the rapidly escalating prices of new drugs to treat cancer, autoimmune diseases, HIV/AIDS, diabetes, heart disease, and a range of other diseases and conditions. This crisis is in the context of an aging population, which has high incidence of cancer and other diseases for which drug prices are high and many consider too high to be sustainable for a health system that aspires to universal access.

In 2010, the percent of the U.S. population 65 years or older was 13 percent. By 2020, the percentage is expected to be 16.1 percent. By 2040, 20 percent, or one in five persons.

Table 1: United States, Population 60+ and 65+

	Percent Age 60 and older	Percent Age 65 and older
2010	18.4%	13.0%
2020	22.2%	16.1%
2030	24.7%	19.3%
2040	25.1%	20.0%
2050	25.5%	20.2%

Another way to look at this is the so called age dependency ratio. There are several one can consider. For the United States, of particular interest is the ratio of the population 65 or older to the population ages 25 to 64. In 2014, that ratio was 28.1 percent, meaning there were 3.56 persons ages 25 to 64, for each person 65 or older. By 2030, the U.S. dependency ratio is expected to be 42.4 percent, or 2.36 persons 25 to 64 for every person 65 or older.

Table 2 compares percent of populations 65 or over in 2014, for the United States and other TPP members, as well as for Brazil, China and India, and four categories of countries based upon incomes, as well as the projected old-age dependency ratio for the years 2015, 2030 and 2040.

What is clear from Table 2 is that the lower income countries typically have relatively younger populations. To the extent the TPP is locking in higher prices for cancer drugs and other

illnesses that are associated with aging, it is placing a relatively greater burden on the United States and other countries with higher old-age dependency ratios.

Table 2: Population 65 and over 2014, and Age dependency ratios going forward, for TPP member countries, with additional comparisons.

		Population ages 65 and above (% of total)	Old-age dependency ratio (% of population aged 65+ per population 25-64)			
		2014	2015	2030	2040	
TPP Members						
Japan		25.7	51.4	62.9	76.4	
Canada		15.7	29.3	47.3	51.9	
Australia		14.7	28.4	39.3	43.9	
New Zealand		14.4	29.1	44.2	50.9	
United States		14.4	28.1	42.4	45.4	
Singapore		11.1	19.6	43.1	60.4	
Chile		10.7	20.5	33.1	44.1	
Peru		6.7	14.4	20.3	26.5	
Vietnam		6.6	12.6	23.1	32.0	
Malaysia		6.3	11.5	18.1	23.4	
Mexico		5.7	13.6	19.9	27.8	
Brunei Darussalam		4.2	7.9	19.9	32.8	
Key countries not in the TPP						
Brazil		7.6	14.9	24.7	32.8	
China		9.2	16.0	30.3	47.6	
India		5.5	11.9	16.4	20.2	
High-income countries		8.1	30.0	43.0	49.6	
Upper-middle-income countries		8.3	15.4	26.8	38.7	
Lower-middle-income countries		5.2	11.6	15.4	18.6	
Low-income countries		3.4	10.0	10.0	10.8	

To the extent that USTR sees middle income countries as increasingly important competitors to the United States, note that the United States old-age dependency ratio for 2030 is projected to

be 42.4 percent, compared to 26.8 percent for upper middle income countries and 15.4 percent for lower middle income countries. The United States may be imposing pain on these countries, but even more so on itself.

Note also that PhRMA membership reported R&D outlays have been declining as a percentage of global sales of pharmaceutical drugs, while non-PhRMA member outlays, including in particular R&D outlays in Europe and Asia, appear to be increasing in importance, making the assumption of U.S. comparative advantage less compelling.

And, while the U.S. pharmaceutical lobby is well organized and politically active in Washington, DC, it is all of the other U.S. industries that have to pay for the higher drug prices, and to the extent that the United States pays more than other countries, it makes our non-pharma companies less competitive, something that the USITC should attempt to quantify.

2. The TPP E-Commerce chapter has a strange provision banning requirements to transfer or provide access to software source code that was never debated or vetted.

When the secret text to the TPP was finally released, there were a number of surprises. One was Article 14.17 in the E-Commerce chapter, a provision that had not been debated, and was not widely vetted, concerning the transparency of software source code.

Article 14.17: Source Code

1. No Party shall require the transfer of, or access to, source code of software owned by a person of another Party, as a condition for the import, distribution, sale or use of such software, or of products containing such software, in its territory.
2. For the purposes of this Article, software subject to paragraph 1 is limited to mass-market software or products containing such software and does not include software used for critical infrastructure.
3. Nothing in this Article shall preclude:
 - (a) the inclusion or implementation of terms and conditions related to the provision of source code in commercially negotiated contracts; or
 - (b) a Party from requiring the modification of source code of software necessary for that software to comply with laws or regulations which are not inconsistent with this Agreement.

4. This Article shall not be construed to affect requirements that relate to patent applications or granted patents, including any orders made by a judicial authority in relation to patent disputes, subject to safeguards against unauthorised disclosure under the law or practice of a Party.

In defending the provision, USTR indicated that companies were concerned about requests for source code from China. But since China is not a member of the TPP, the impact is to prevent the United States and other TPP member countries from insisting on open source code. The provision is somewhat narrow, it does not apply to government procurement, “critical infrastructure” (whatever that means), it is limited to mass market software, and it does not interfere with contracts between private parties, fact noted by the Software Freedom Law Center in its conclusion that the provision provides “no harm, no foul.”³

However, in the areas where the provision does apply, it provides an astonishing broad attack on government authority to regulate software applications, including areas where security, privacy, fraud, interoperability or other issues are at play. Klint Finley of Wired was quick to question whether or not the provision would prevent governments from requiring manufacturers of automobiles or other things to open the code for certain software: ⁴

Volkswagen’s infamous emissions-test-subverting software lurked in cars for years before it was discovered by regulators. The company got away with it for so long, in part, because it’s hard to actually tell what’s going on within the embedded computers of an automobile.

One way to deal with the issue would be to require that certain types of companies, like automakers, release the software code that powers their products to the public, so that researchers could evaluate deceitful practices as well as security flaws. A less extreme solution, suggested by Zeynep Tufekci in the [New York Times](#) this year, would be to simply require automakers to release code to auditors, the same way the manufacturers of casino slot machines must open their code to gambling regulators.

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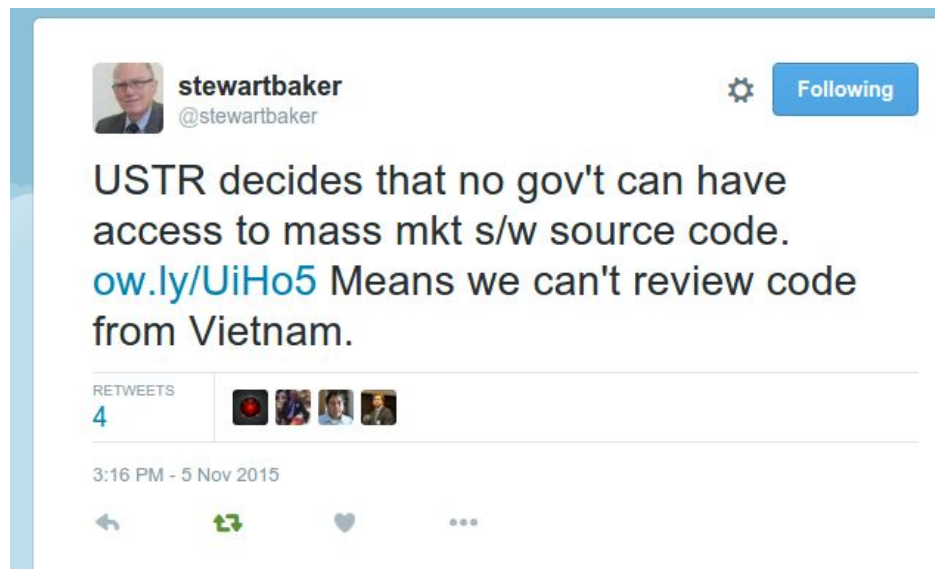
The proposal includes an exception for critical infrastructure, but it’s not clear whether software involved in life or death situations, such as cars, airplanes, or medical devices would be included.

³ TPP Article 14.17 & Free Software: No Harm, No Foul, November 11, 2015. IP-Watch. <http://www.ip-watch.org/2015/11/24/tpp-article-14-17-free-software-no-harm-no-foul/>

⁴ Klint Finley, Trade Pact Could Bar Governments From Auditing Source Code, November 5, 2015. Wired. <http://www.wired.com/2015/11/trade-pact-could-bar-governments-from-auditing-source-code/>

Forcing companies to publish their source code won't necessarily solve the problem of cheating or buggy software. Huge security problems have been known to linger for years in open source projects that had too few security audits. And there are ways to encourage companies to release their source code that don't involve passing import laws. But the TPP, as written, would remove one powerful option in the fight to open the Internet of Things.

Others, including Stewart Baker, a former NSA General Counsel, commented that "USTR decides that no gov't can have access to mass mkt s/w source code. Means we can't review code from Vietnam."⁵



Stewart Baker was concerned about countries or criminals using the TPP provision to hide spyware aimed at people living the United States.

The United States has on more than one occasion required software publishers to open parts of their software code, in order to address competition concerns. In various cases involving Microsoft, the United States and the European Union has insisted on third party access to software APIs and protocols. Access to the source code of MySQL was a major issue in the EU competition review of the Oracle acquisition of Sun Microsystems.⁶

There is considerable interest today in requiring Google to be more transparent about its searching algorithms, or in ensuring that certain platforms, such as the Android operating system, are sufficiently open. And, as Klint Finley noted earlier, the explosive growth of the Internet of Things⁷ will make interoperability, security, privacy and other software related issues

⁵ Baker inadvertently cited the wrong TPP chapter.

⁶ Case No COMP/M.5529 – ORACLE/ SUN MICROSYSTEMS, January 21, 2010.
http://ec.europa.eu/competition/mergers/cases/decisions/m5529_20100121_20682_en.pdf

⁷ https://en.wikipedia.org/wiki/Internet_of_Things

increasingly more important, not to mention the more speculative but plausible dangers and risks that non-auditable source source will present in the future.

The non-transparency of software source code is of course a product of a non-transparent negotiation, and ironic evidence that secrecy presents risks -- in this case, the risk that a few government officials will create a permanent rule that no one had a chance to debate on its own merits, a rule that will have unintended consequences and negative consequences for competition, privacy and security, and make it harder to detect and overcome fraud.

3. The TPP Technical Barriers to Trade Chapter has a peculiar provision banning the collection of data on drug sales revenue, prices and marketing costs.

Another surprise in the TPP was a provision in Chapter 8, on technical barriers to trade that places restrictions on mandated disclosures of information about drug or medical device prices, sales revenue or “related financial data.”

CHAPTER 8 TECHNICAL BARRIERS TO TRADE,

ANNEX 8-C: PHARMACEUTICALS

7bis. Each Party shall make its determination on whether to grant marketing authorisation for a specific pharmaceutical product on the basis of:

- (a) information, including, where appropriate, pre-clinical and clinical data, on safety and efficacy;
- (b) information on manufacturing quality of the product;
- (c) labelling information related to safety, efficacy and use of the product; and
- (d) other matters that may directly affect the health or safety of the user of the product.

To this end, no Party shall require sale or related financial data concerning the marketing of the product as part of such a determination. Further, each Party shall endeavour not to require pricing data as part of the determination.

Annex 8-E: Medical Devices

8. Each Party shall make its determination on whether to grant marketing authorisation for a specific medical device on the basis of:

- (a) information, including, where appropriate, clinical data, on safety and efficacy;

- (b) information on performance, design and manufacturing quality of the product;
- (c) labelling information related to safety, efficacy, and use of the product; and
- (d) other matters that may directly affect the health or safety of the user of the product.

To this end, no Party shall require sale, pricing, or related financial data concerning the marketing of the product as part of such a determination

While there is an argument in favor of focusing drug registration decisions on medical considerations only, there is also a paucity of information on drug prices, revenues and other relative information on the economics of the pharmaceutical market.

It is certainly desirable to require drug and device makers to provide information about product prices, revenues, and a variety of related financial data, including the outlays on R&D and marketing of products. These are the very topics that the State of California and other state governments are seeking to obtain from drug companies, but it is much easier to mandate such disclosures at the federal level.

Much of the pricing and sales data for drugs is now controlled by IMS, the company that holds a near global monopoly on the most detailed information on sales revenue and pricing of drugs.

Other "related financial data concerning the marketing of the product" might include data on R&D outlays, a topic shrouded in unhelpful secrecy and subject to too much controversy, when the facts exist and could be shared. From the text, it is not that clear how far the ban on requiring financial data extends, and to which activities of a regulatory agency or another government body would be constrained by these provisions.

4. The TPP provisions on damages for infringement of intellectual property rights are contrary to U.S. laws, contrary of proposed legislation to expand limits on damages to orphan copyrighted works, and may restrict legislative reforms on other issues.

KEI has on numerous occasions raised objections to language in various trade agreements, including now in the TPP, which mandate aggressive standards for damages relating to the infringement of intellectual property rights. We can imagine cases where very high damages associated with infringements are appropriate, but we are also aware of countless exceptions to the general case. The TPP norms do not provide for general exceptions to obligations, and the exceptions that are provided are not sufficient.

The general obligations on damages are set out in Article 18.74, paragraphs 1, 2, 3 and 4, and covers “any intellectual property right covered in this Chapter.”

Article 18.74: Civil and Administrative Procedures and Remedies

1. Each Party shall make available to right holders civil judicial procedures concerning the enforcement of any intellectual property right covered in this Chapter.[108]

2. Each Party shall provide that its judicial authorities have the authority to order injunctive relief that conforms to Article 44 of the TRIPS Agreement, including to prevent goods that involve the infringement of an intellectual property right under the law of the Party providing that relief from entering into the channels of commerce.

3. Each Party shall provide [109] that, in civil judicial proceedings, its judicial authorities have the authority at least to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person’s intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity.

4. In determining the amount of damages under paragraph 3, each Party’s judicial authorities shall have the authority to consider, among other things, any legitimate measure of value the right holder submits, which may include lost profits, the value of the infringed goods or services measured by the market price, or the suggested retail price.

. . .

108 For the purposes of this Article, the term “right holders” shall include those authorised licensees, federations and associations that have the legal standing and authority to assert such rights. The term “authorised licensee” shall include the exclusive licensee of any one or more of the exclusive intellectual property rights encompassed in a given intellectual property.

109 A Party may also provide that the right holder may not be entitled to any of the remedies set out in paragraphs 3, 5 and 7 if there is a finding of non-use of a trademark. For greater certainty, there is no obligation for a Party to provide for the possibility of any of the remedies in paragraphs 3, 5, 6 and 7 to be ordered in parallel.

One of our main concerns is the requirement, in Article 18.74.4, that “judicial authorities shall have the authority to consider, among other things, any legitimate measure of value the right holder submits, which may include. . . the value of the infringed goods or services measured by the market price, or the suggested retail price.” This is an example of legislation by lobbying the USTR, and of lazy drafting. The United States is, by far, the country where exceptions are used the most in the area of remedies for infringement. We deliberately allow infringement of copyrighted and patented works by the federal government, so the notion that damages should deter infringement is contrary to 28 USC 1498, and many other provisions in U.S. law. We have special limits on damages for the infringement of patents on biologic drugs, designed to induce transparency of the biologic drug patent landscape, in order to reduce the risks to biosimilar competitors, in 35 USC 271(e)(6)(B-C). We limit the remedies for infringement of patents on nuclear energy. We limit the remedies for the infringement of a patent involving a surgical procedure on a body, in 35 USC 287(c).

One might argue that some of the areas where the United States provides limitations on damages, by statute, that are inconsistent with the TPP’s general provisions, are allowed under Article 18.74.2, although that is not clear at this point.

The TPP provisions in Article 18.74 - paragraphs 5-12 provide a number of additional sanctions for infringement, including several special provisions relating to copyright and trademark cases. Trademark also receives certain exceptions to damages in footnote 109 of the intellectual property chapter. All of the copyright provisions are contrary to the proposals by the June 2015 by the Register of Copyright for legislation to expand access to orphan works.

One of our commentaries on this issue was a July 28, 2015 article in IP-Watch, titled: The TPP’s Reckless Proposals For Damages Will Have Negative Impact On Future Reform Of IPR Regimes.
<http://www.ip-watch.org/2015/07/28/the-tpps-reckless-proposals-for-damages-will-have-negative-impact-on-future-reform-of-ipr-regimes/>

5. State Sovereign Immunity.

Special attention should be given to the fact that the TPP provisions on damages are inconsistent with the U.S. Supreme Court decision on State Sovereign Immunity.

KEI refers here to a video produced by Zack Struver and Tazio De Tomassi, on July 26, 2015, during the negotiations on the intellectual property and investment chapters of the Trans Pacific Partnership (TPP) trade agreement. The video points out that USTR is ignoring 1999 US Supreme Court Decision in FLORIDA PREPAID v COLLEGE SAVINGS (98-531) 527 U.S. 627 (1999) and related cases which hold that U.S. states cannot be sued for patent, trademark (or copyright) infringement under the provisions of the 11th Amendment to the U.S. constitution. USTR’s proposals on remedies make the U.S. government liable for such infringements, under

the TPP private sector arbitration provisions in the Investor State Dispute Settlement (ISDS).
<http://www.keionline.org/node/2293>

Note that the current doctrine of state immunity from copyright and patent infringement cases is protecting state universities from aggressive copyright litigation, and provide a de-facto research exception for patents in academic institutions. That is a lot to throw away in the TPP.