Trans-Pacific Partnership IP Provisions Relevant to Access to Medicines

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What is the TPP?

(according to USTR…)

Images from the USTR twitter feed leave a warm and cuddly impression.

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By the numbers:

12 Countries

(Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, United States, Vietnam)

7 years of negotiation

5000+ pages

127 pages of emails between U.S. government officials and corporate lobbyists returned via IP-Watch FOIA as of 2013 (http://keionline.org/node/1833)

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By the numbers…

6 of 12 TPP countries considered “developing” by the U.N.

$1,890 Vietnam GNI per capita (2014)

$19,100,000,000:

Gilead 2015 sales on Sovaldi and Harvoni (http://www.fiercepharma.com/story/gileads-hep-c-juggernaut-continues-q4-even-us-sales-fall/2016-02-02)

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By the numbers…

4 leaks of the IP Chapter

(3 wikileaks + 1 via KEI)

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IP Chapter re A2M:

Evergreening (patentable subject matter)
Patent Term Adjustments
Sui Generis Exclusivity (small molecules and biologics)
Damages

Investment Chapter:

Investor-State Dispute Settlement

Patent Evergreening

Article 18.37

"2. …each Party confirms that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product. A Party may limit those new processes to those that do not claim the use of a product as such."

"Typically, when you evergreen something, you are not looking at any significant therapeutic advantage. You are looking at a company's economic advantage."

--Dr. Joel Lexchin, Professor
York University School of Health Policy and Management

(Collier, Roger. "Drug Patents: The Evergreening Problem." CMAJ: Canadian Medical Association Journal 185.9 (2013): E385-E386. *PMC*. Web. 25 Jan 2016.)

Patent Extensions

Article 18.48

"2. With respect to a pharmaceutical product that is subject to a patent, each Party shall make available an adjustment [46] of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process."

"Unreasonable" = undefined

Footnote 46 provides that alternatively a Party may provide an analogous *sui generis* form of protection

Sui Generis Exclusivity

Article 18.50 (small molecules)

1.(a)-(b): At least **5 years** protection against generic manufacturer gaining marketing approval on basis of originator's (i) safety/ efficacy data or (ii) marketing approval. Runs from date of originator approval in the date of the TPP Party.

2.(a)-(b): Additional **3 year** period of exclusivity where an existing product is approved for a new indication/use/method, or, alternatively, an additional five year period for new product containing a new chemical entity.

Sui Generis Exclusivity

Article 18.51 (**biologics**)

1.(a): a period of at least **8 years**, or alternatively, (b) **at least five years** plus **"other measures"** to **"deliver a comparable outcome in the market."**

TPP countries with **ZERO** exclusivity on biologics pre-TPP:
Brunei
Mexico
Peru
Vietnam

Damages

Article 18.74 (Civil and Administrative Procedures and Remedies)

"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 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."**

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[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 a non-use of a trademark…"

Concerns re: Damages

Some U.S. laws specify how damages are to be calculated (actual damages, lost profits, etc.), sometimes setting the rate to zero

Lack of carveout for statutory limitations (a la FN 109)

Some U.S. law examples utilizing “reasonable royalty”:
Biologics Price Competition and Innovation Act (BPCIA)
Sen. Sanders compulsory licensing proposal (July 2015)
re: Veterans Admin. (http://keionline.org/node/2290)

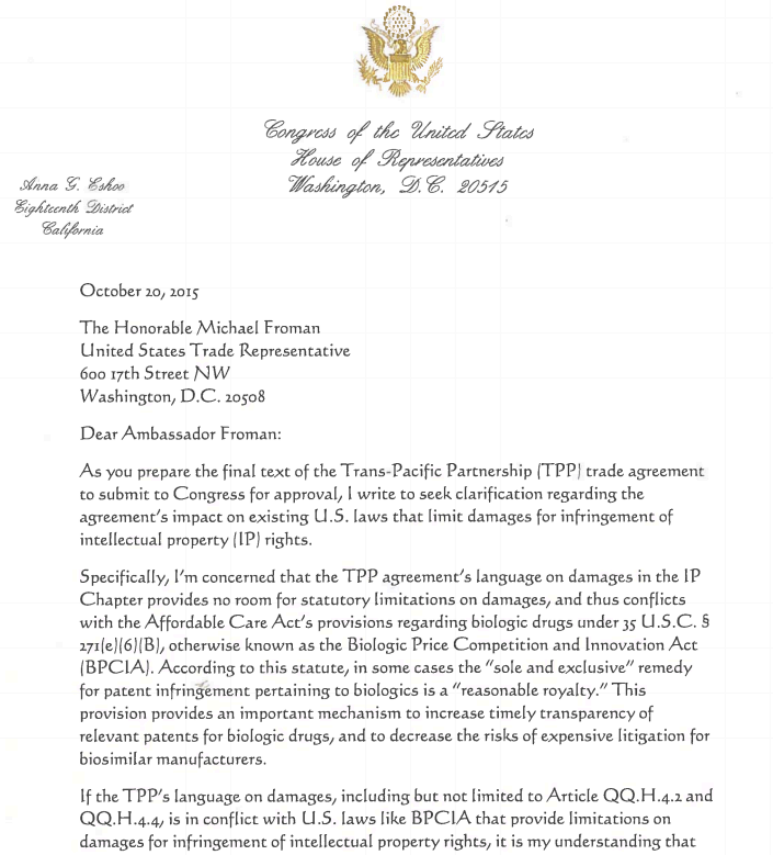
Concerns re: Damages

Letter from Rep. Eshoo (D-CA) to Michael Froman, Oct 20 2015:

"…in some cases the 'sole and exclusive' remedy for patent infringement pertaining to biologics is a 'reasonable royalty.'"

"I'm concerned that the TPP agreement's language on damages in the IP Chapter provides no room for statutory limitations on damages…"

(www.keionline.org/node/2349)



Congress of the United States
House of Representatives
Washington, D.C. 20515

Anna G. Eshoo
Eighteenth District
California

October 20, 2015

The Honorable Michael Froman
United States Trade Representative
600 17th Street NW
Washington, D.C. 20508

Dear Ambassador Froman:

As you prepare the final text of the Trans-Pacific Partnership (TPP) trade agreement to submit to Congress for approval, I write to seek clarification regarding the agreement's impact on existing U.S. laws that limit damages for infringement of intellectual property (IP) rights.

Specifically, I'm concerned that the TPP agreement's language on damages in the IP Chapter provides no room for statutory limitations on damages, and thus conflicts with the Affordable Care Act's provisions regarding biologic drugs under 35 U.S.C. § 271(e)(6)(B), otherwise known as the Biologic Price Competition and Innovation Act (BPCIA). According to this statute, in some cases the "sole and exclusive" remedy for patent infringement pertaining to biologics is a "reasonable royalty." This provision provides an important mechanism to increase timely transparency of relevant patents for biologic drugs, and to decrease the risks of expensive litigation for biosimilar manufacturers.

If the TPP's language on damages, including but not limited to Article QQ.H.4.2 and QQ.H.4.4, is in conflict with U.S. laws like BPCIA that provide limitations on damages for infringement of intellectual property rights, it is my understanding that

Investment Chapter

Art. 9.1 (Definitions)

"**investment** means every asset that an investor owns or controls…Forms that an investment may take include:

…

(f) intellectual property rights"

Art. 9.7 (Expropriation and Compensation)

"(5) This Article shall not apply to the issuance of compulsory licences granted in relation to intellectual property rights **in accordance with the TRIPS Agreement**, or to the revocation, limitation or creation of intellectual property rights, **to the extent that the issuance, revocation, limitation or creation is consistent with Chapter 18 (Intellectual Property) and the TRIPS Agreement.**

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[19] For greater certainty, the Parties recognise that, for the purpose of this Article, the term 'revocation' of intellectual property rights includes the cancellation or nullification of those rights, and the term 'limitation' of intellectual property rights includes exceptions to those rights."

Recent/Ongoing ISDS Cases

KEI
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TransCanada v United States

TC seeking $15 Billion for cancellation of Keystone XL pipeline (via NAFTA ISDS)

Eli Lilly v Canada

EL challenging Canada since 2013 under NAFTA ISDS ($500M) re: Canada invalidation of EL patents

Philip Morris v Australia

PM brought ISDS action against Australia in 2012 re plain packaging tobacco law. Just ended in Dec. 2015.

Political Reality?

U.S. implementing legislation timeline is tight

Feb 4 signing

→ wait at least 30 days to introduce legislation

→ max 105 days from signing, ITC report to Congress on probable economic effects

→ Congressional consideration

Election Year…

Dem Candidates – all opposed

Republicans – Trump opposes, Cruz somewhat back and forth, Kasich "PPT"

What Could Have Been?

Delinkage (R&D costs // price)
Orphan Drug Tax Credit
Prize Funds
R&D Commitments
Transparency in Clinical Trial Data and R&D Costs

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