July 10, 2015

Emily Bleimund
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Department of Health and Human Services
Washington, DC

via: emily.bleimund@hhs.gov

Dear Emily Bleimund,

We are writing to express our concern about three specific features of the Trans Pacific Partnership (TPP), and ask that U.S. Department of Health and Human Services (HHS) and others agencies fix things in the inter-agency review.

1. Room for exceptions to exclusive rights in pharmaceutical and biologic drug test data.

With respect to the provisions on test data for pharmaceutical and biologic drugs, we are of course opposed to locking the U.S. and everyone else into the 12-year term for biologic drugs, but also call attention to the issue of exceptions to the rights. In the WTO TRIPS agreement, when exclusive rights are required, there are also the possibility of exceptions, and certainly so in the cases of patents, copyrights, trademarks, industrial designs and layout-designs (topographies) of integrated circuits, and even for the protection of undisclosed information. We are concerned that the TPP will create a super-right for test data, one that does not allow for exceptions.

It would not take much to create a space for exceptions in the TPP, including, for example, by just saying something along the lines of Article 37.2 of the TRIPS, regarding semiconductor layout designs, which says:

> 2. The conditions set out in subparagraphs (a) through (k) of Article 31 shall apply mutatis mutandis in the event of any non-voluntary licensing of a

layout-design or of its use by or for the government without the authorization of the right holder.

Something like this would also be consistent with the provisions of the May 10, 2007 agreement, which included a promise to *"include an exception to the data exclusivity obligation for measures to protect public health in accordance with the Doha Declaration and subsequent protocols for its implementation."*

There are cases where the U.S. itself will want to have exceptions to test data. One such exception is where prices are unreasonable. Another is when the right holder cannot supply the market, such as the recent case involving Fabrazyme, a very expensive drug for Fabry's disease that was severely rationed in the United States, but not in Europe, where a compulsory license case in Germany was used to protect the European supply. In the Fabry case, the FDA allowed a European drug manufacturer to supply some U.S. patients, mitigating to some degree the shortage in the United States.

The U.S. can also face a public health emergency, such as the threat posed in 2001 by shortages of ciprofloxacin to treat certain types of anthrax poisoning, or real or potential threats from Ebola, influenza, or MERS. There are any number of other possible situations where the government may need to break the monopoly on test data used for FDA approval of drugs, including shortages of drugs for cancer or other illnesses. (See, for example, Executive Order 13588 -- Reducing Prescription Drug Shortage).

The United States has also sought to end monopolies on test data in several competition cases involving both the FTC and the U.S. Department of Justice. (We can provide examples if that is needed).

In a related case, involving an exception on non-patented data, a federal judge in Texas recently authorized the non-voluntary use of trade secrets for medical devices in exchange for a running royalty (Sabatino Bianco, M.D. v. Globus Medical, 2:12-cv-00147, E.D. Tex 2014, http://keionline.org/node/2053, John C. Low, "Misappropriation of trade secrets warrants an ongoing 'reasonable royalty,'" August 8 2014).

The system of rights on test data proposed in the TPP needs to be modified or subject to compulsory licensing/cost sharing alternatives when an exclusive rights regime would require a generic or biosimilar supplier to conduct experiments that violate the Declaration of Helsinki on the Ethical Principles for Medical Research Involving Human Subjects (http://www.wma.net/en/30publications/10policies/b3/), a norm referenced in the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual property (http://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf). Note that among other things, the Declaration of Helsinki states:

> When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

Similar ethical concerns arise in animal studies. Animal rights advocates have obtained new rules in the European Union that protect animals from duplicative studies, providing in its place a mandatory cost sharing regime for test data during the term of test data rights.

We anticipate that at some point in time the ethical standards for experiments involving humans will catch up with the standards recognized by the EU for rats, rabbits and other laboratory animals. When this occurs, alternatives to exclusive rights, including cost sharing, (already implemented in the United States and Europe for agricultural test data) should be allowed by the TPP for trials involving humans.

An example of how a national government might want to create a statutory framework for exceptions in text data is Chile Law No. 19.039 on Industrial Property (Consolidated Law approved by Decree-Law No. 3):

> Article 91.– Protection under this paragraph shall not apply where: (a) the holder of the information providing proof indicated in Article 89 has engaged in conduct or practices declared anticompetitive, directly related to the use or exploitation of such information, according to a final or binding decision by the Antitrust Tribunal; (b) on justified grounds of public health, national security, noncommercial public use, national emergency or other extremely urgent circumstances declared so by the competent authority, the protection set out in Article 89 may be terminated; (c) the pharmaceutical product or agricultural chemical is the subject of a compulsory license pursuant to the stipulations in this Law; (d) the pharmaceutical product or agricultural chemical has not been marketed within the national territory by the end of a 12-month period beginning from the date of the health registration or authorization granted in Chile; (e) the application for registration or health authorization of the pharmaceutical product or agricultural chemical that is filed in Chile 12 months D after the first registration or health authorization has been obtained abroad.

2. WTO standards for compulsory licenses should not be modified as part of a secret negotiation, or constrained by a 3-step test.

For reasons that remain unclear, between 2013 and 2014 the United States blocked and eventually eliminated a proposal in the draft IPR text that would have ensured that the TPP article on the restrictions on exceptions to patent rights did not apply to compulsory licenses that

were consistent with Article 31 of the TRIPS agreement. What is important in this respect is that the standard for compulsory licenses, set out in Article 31 of the TRIPS agreement, is not subject to the filter of an additional 3-step test. We have discussed this issue in some detail here: *KEI TPP Briefing note 2015:1 Compulsory licenses on patents and the 3-step test.*

In the WTO TRIPS, the 3-step test is used as a standard for some exceptions, but not others. In particular, the 3-step test is used for exceptions where the safeguards in Article 31 of the TRIPS are *not* observed. Articles 30 and 31 of the TRIPS are separate standards for exceptions. Typically the Article 30 exceptions in the TRIPS are used when there is no notification to the patent holder, and no compensation or remuneration to the patent holder. Examples of Article 30 exceptions would include exceptions for personal use, or the so-called Bolar exception, for research on a drug related to preparing an application to the FDA to sell a generic copy. Article 31 in the TRIPS is the mechanism typically used for compulsory licenses, where there is normally both notification of the patent holder and compensation or remuneration to patent holders, as well as some restrictions on exports. Both Articles in the TRIPS are important, but they are used for different purposes. The Article 30 3-step test is very liberal in terms of procedures, but more restrictive in terms of outcomes. The opposite is true for Article 31. The United States, and other countries, use both Articles in the TRIPS.

Nearly all compulsory licenses on cancer and HIV/AIDS drug patents in developing countries, remedies to anticompetitive practices in the United States, important cases in the UK and Germany, and to some degree, the U.S. Department of Defense authority to use patents "by or for" the government under 28 USC 1498(a), benefit from the flexibility in Article 31 to allow third parties to use patents with permission from right holders. Changing these standards in the TPP, by subjecting compulsory licenses to the 3-step test, is inappropriate, and probably unintended by some negotiators.

We have compiled a table of the provisions on allowed exceptions and limitations to patent rights in 13 U.S. FTAs, beginning with NAFTA. The agreements vary considerably, with some only having a 3-step test, one not having a 3-step test at all, some having specific restrictions on the types of compulsory licenses allowed, and some simply making some references to the Doha Declaration on TRIPS and Public Health, with ambiguous legal meaning, as regards what a country can do as regards compulsory licensing of patents. What we ask is that the TPP does not introduce any new standards for compulsory licensing of patents, recognizing that the WTO already regulates this activity in some detail.

We are told by various sources that in 2015, USTR, Australia and others have discussed or proposed some type of fix to protect Article 31 compulsory licenses, and that this issue has been clarified. KEI would like to see the text that addresses this issue, which is perhaps only a sentence. PhRMA and several of their members have access, and we would like to see for ourselves if the clarification addresses our concerns.

Here we note that the U.S. laws on compulsory licenses involve diverse statutes and subject matter. We have statutes that enable compulsory licensing of patents for nuclear energy, the Clean Air Act, biologic drugs, the Tennessee Valley Authority, energy storage and efficient lighting technologies, use by or for federal agencies, and a large number of cases done under competition law, or as a limitation on remedies to infringement, including for example, USTR's 2013 decision to use Section 337 of the Tariffs Act of 1930 to allow Apple to infringe patents held by Samsung on iPhones and IPADs.

Mere references to the WTO Doha Declaration on TRIPS and Public Health not only are ambiguous as to what exceptions are allowed, but they narrow the space for compulsory licenses to a single subject matter, not covering all medical technologies, and ignoring the importance of all non-medical technologies, including those relevant to standards essential patents, such as the dispute over UNOCAL patents on reformulated gasoline.

3. The TPP standards for damages are contrary to several U.S. statutes, and require an amendment of the Affordable Care Act incentives to disclose patent landscape on biologic drugs.

KEI is frustrated that the damages section in the TPP includes language that rules out any statutory standards for damages that would prohibit a judge from awarding "any legitimate measure of value the right holder submits, which may include lost profits, the value of the infringed goods or service measured by the market price, or the suggested retail price." This standard, which goes beyond U.S. standards, is found in paragraphs 2 and 4 of the Article on civil procedures and remedies for intellectual property rights.

> **TPP Negotiations, Ho Chi Minh**
> **IP Group**
> **Intellectual Property [Rights] Chapter May 16, 2014**
>
> **Article QQ.H.4: {Civil Procedures and Remedies / Civil and Administrative Procedures and Remedies}**
>
> ...
> 2. Each Party shall provide[156] that in civil judicial proceedings its judicial authorities have at least 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.[157]
>
> …

4. In determining the amount of damages under paragraph 2, its judicial authorities shall have the authority to consider, inter alia, any legitimate measure of value the right holder submits, which may include lost profits, the value of the infringed goods or service measured by the market price, or the suggested retail price.

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156 - A Party may also provide that the right holder may not be entitled to [AU oppose: either] [AU propose: any] of the remedies set out in [AU oppose: 2 and 3] [AU propose 2, 3 and 8] in the case of a finding of non-use of a trademark. It is understood that there is no obligation for a Party to provide for the possibility of the [AU: any of the] remedies in 2, 3, 7 and 8 to be ordered in parallel.

157 - ***Negotiator's Note: US is withdrawing reasonable royalties for patent infringement ad ref pending outcome***

We are preparing a separate note for negotiators dealing only with the issue of damages in the TPP. Here, however, we begin with a simple observation -- the TPP would require an amendment to the Affordable Care Act (ACA) limitations on damages, in cases where the holder of patents on a biologic drug fails to provide timely and constructive disclosure of the patent landscape on a biology drugs. Among other things, 35 U.S.C. Section 271(6)(B) of the US patent law provides that when patents are not timely disclosed to a potential competitor, the damages for the infringement of a biological product "shall be a reasonable royalty."

35 U.S.C. § 271 : Infringement of patent

(e)(6)(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

The rationale for limiting damages in 35 U.S.C. 271(e)(6)(B) is to create an incentive for the biologic drug manufacturer to be more transparent about patent landscapes, and thus reduce the risks to the biosimilar drug company. The TPP would make the U.S. at risk for litigation under ISDS and sizable damages if this provision in the ACA is not changed.

There are of course other areas where U.S. statutes have special standards for damages. For example, in the area of nuclear energy patents, according to 42 U.S.C. 2184, "the measure of damages shall be the royalty fee determined pursuant to section 42 U.S.C. 2187 (c)", which among other things, would lower damages when "such patent was developed through federally

financed research," or when "cost to the owner of the patent of developing such invention or discovery or acquiring such patent" was small, an approach that some think could be usefully extended to drug patents.

In the area of copyright, the "suggested retail price" is not consistent with 17 U.S.C. 504(b), which provides for "actual damages and any additional profits of the infringer," which it defines as:

> actual damages suffered by him or her as a result of the infringement, and any profits of the infringer that are attributable to the infringement and are not taken into account in computing the actual damages. In establishing the infringer's profits, the copyright owner is required to present proof only of the infringer's gross revenue, and the infringer is required to prove his or her deductible expenses and the elements of profit attributable to factors other than the copyrighted work.

Here actual revenues less "deductible expenses" and less "elements of profit attributable to factors other than the copyrighted work" provide a more reasonable and different statutory standard than what is proposed in the TPP.

But in copyright, there are also exceptions even to this standard. The U.S. fashions some copyright exceptions as limitations on damages. For example, in the past, the Librarian of Congress was "authorized and directed to arrange, index and microfilm the papers of the Presidents of the United States .. . . " and " Neither the United States nor any officer or employee of the United States shall be liable for damages for infringement of literary property rights by reason of any activity authorized by this Act." [ORGANIZING AND MICROFILMING OF PRESIDENTIAL PAPERS; APPROPRIATION, Pub. L. 85-147, Aug. 16, 1957, 71 Stat. 368, as amended by Pub. L. 87-263, Sept. 21, 1961, 75 Stat. 544; Pub. L. 88-299, Apr. 27, 1964, 78 Stat. 183.] More recently, the U.S. Copyright Office has proposed legislation to limit damages for the infringement of "orphaned" copyrighted works. (http://copyright.gov/orphan/). According to its June 2015 Report on *Orphan Works and Mass Digitization*, the Register of Copyrights noted:

> The uncertainty surrounding the ownership status of orphan works does not serve the objectives of the copyright system. For good faith users, orphan works are a frustration, a liability risk, and a major cause of gridlock in the digital marketplace.153 The consequences of this uncertainty reverberate through all types of uses and users, all types and ages of works, and across all creative sectors.154 By electing to use a work without permission, users run the risk of an infringement suit resulting in litigation costs and possible

> damages. By foregoing use of these work, a significant part of the world's cultural heritage embodied in copyrighted-protected works may not be exploited and may therefore fall into a so-called "20th-century digital black hole."155 [footnotes omitted]

To address this problem, the U.S. Copyright Office has proposed new legislation. Contrary to the un-bracketed language in the TPP on damages, the Copyright Office wants to create new limitations on damages, and to constrain the Court's discretion in considering the aggressive measures proposed in the TPP (which are actually more aggressive for copyright than for patents). In its analysis of the proposed legislation for orphan works, the Copyright Office explains that not only are damages limited by the bill, but they recommended a complete elimination of damages for certain nonprofit entities:

> Section 514(c)(1) Limitations on Remedies - Monetary Relief Monetary relief (including actual damages, statutory damages, costs, and attorney's fees) shall be limited to an order to pay reasonable compensation to the owner of the infringed copyright for use of the infringed work. No monetary relief may be made if the infringer is a nonprofit educational institution, museum, library, archives, or public broadcaster (or employee thereof), and proof by preponderance of the evidence is made that infringement was performed without purpose of direct or indirect commercial advantage; was primarily educational, religious, or charitable; and, after Notice of Claim of Infringement and good faith investigation, infringement promptly ceases. Additionally, a court may take the value added to an infringed work by virtue of its registration into account in determining reasonable compensation.

There are several other areas where U.S. intellectual property laws provide exceptions to remedies for infringement that are not allowed by the plain language of the TPP on remedies, which anticipates no exceptions at all.

Finally, on the topic of damages, the TPP language inartfully applies to "intellectual property" which is defined in the TPP as everything in the TRIPS:

> Article QQ.A.1: {Definitions} For the purposes of this Chapter intellectual property refers to all categories of intellectual property that are the subject of Section 1 through 7 of Part II of the TRIPS Agreement.

The TPP definition includes not only patents, trademarks and copyrights, but also pharmaceutical test data, an area of intellectual property where the United States does not provide for damages when those rights are infringed. If the U.S. wanted to create a liability rule for non-voluntary use of pharmaceutical drug test data, based upon estimates of the risk adjusted investments in the creation of such data, it may confront claims that non-voluntary use is subject to enormous damages based upon the suggested retail price of drugs. These types of unintended consequences can be avoided by simply making reference to the TRIPS standards for damages as the general case, and then adding whatever specific enhancements the US wants, particularly in the areas of copyright or trademarks.

Concluding remarks

Within the constraints of the secrecy that Ambassador Froman favors for this negotiation, the USTR subject matter staff, including Probir Mehta, have been very accessible and willing to discuss our concerns. We appreciate the opportunity to provide input into the substantive provisions in the TPP, and we are optimistic that all of the concerns identified here can be resolved before or during the Maui talks. That said, we are frustrated that in 2015 we are still addressing the same concerns about damages we have raised throughout the ACTA and TPP negotiations, that the Administration has yet to provide clear language allowing robust exceptions for rights in pharmaceutical test data, and that the status and standards for exceptions to patent rights (including compulsory licenses) are regulated at all in the TPP when there already exists a well understood standard in the WTO for exceptions.

Given the size of the TPP and the ambition of the chapters on intellectual property, transparency, investments, government procurement and services, it may have a larger impact on global pricing and availability of medicines than the WTO TRIPS agreement. It will be extremely difficult to modify the agreement, and it empowers private for-profit companies to have an aggressive role in interpreting and enforcing the text of the agreement. The United States has a more diverse, complex and robust set of exceptions for intellectual property rights than any of our trading partners, and the final TPP text should not prevent the United States or other countries from using such exceptions to address legitimate concerns about abuses of intellectual property rights, or to promote the public interest. You are among the handful of people who can influence the outcome of the negotiation. We are counting on you, and everyone we have cc'd on this letter.

Sincerely,

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Knowledge Ecology International (KEI)

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Knowledge Ecology International (KEI)

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