Notice of Intent to Testify

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Hearing Statement of Knowledge Ecology International on the 2013 Special 301 Review

About Knowledge Ecology International

Knowledge Ecology International (KEI) is a non-profit, non-governmental organization based in Washington, DC with offices also in Geneva, Switzerland. KEI is an organization that searches for better outcomes, including new solutions, to the management of knowledge resources, particularly in the context of social justice.

KEI offers the following comments on the 2013 Special 301 Review. First, however, we note our objections to the annual review and Special 301 process, which is a highly time consuming, repetitive and unnecessary process.

Extension for Least-Developed-Countries

We have deep concerns regarding least-developed countries and any requirements for them to implement TRIPS standards. We strongly urge the United States to support least-developed countries an extension of the transition period under Article 66.1 of the TRIPS Agreement. The current extension period for least-developed countries runs through 1 July 2013 and Haiti requested an extension of this period; we ask the United States to support Haiti's request and grant an extension to all least-developed countries. In granting such an extension, no conditions should be placed on least-developed countries. In its 2012 Special 301 Report, USTR noted that "In December 2011, WTO Ministers decided to invite the TRIPS Council to give full consideration to a duly motivated request from LDC members for an extension of the TRIPS Agreement transition period. The U.S. supports this decision and looks forward to continuing to work with LDCs and other WTO members in this regard," and we call on the United States to fulfill its support for least-developed countries and work to grant the requested extension.

Should WTO members fail to approve an extension, we strongly request the United States to exempt least-developed countries from any scrutiny under the Special 301 process. USTR should continue to recognize the particular challenges faced by least-developed countries and not place any least-developed country on its Special 301 lists.

Compulsory Licenses

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) preserved a number of important flexibilities for states to use, including the right to grant compulsory licenses. We object to the practice of USTR of placing countries on its Special 301 watch lists

for issuing, or threatening to issue, a compulsory license. Although the United States claims to support the sovereign right of states to grant compulsory licenses, USTR has repeatedly placed countries on its watch lists for exercising this right, including Ecuador, Thailand and India.

We note, for example, our concern over USTR's 2012 Special 301 report which singled out and expressed concern over India's compulsory license for patents on Nexavar/sorafenib, a cancer drug that was priced a $68,000 per year in India, a price well beyond the reach of the vast majority of patients in the country.

Placing other countries on the Special 301 list seems hypocritical considering the practice in the United States of granting judicial compulsory licenses after the Supreme Court held in *eBay v. MercExchange* that injunctions are not automatically granted in all cases of intellectual property infringement. While the United States commonly grants judicial compulsory licenses, it seeks to eliminate the right of others to exercise this important flexibility. With respect to medicines, pressuring states not to grant compulsory licenses can severely and detrimentally impact the public health of its citizens, particularly when medicines are priced grossly out of reach of the majority of its population.

Patent Linkage

In the 2012 Special 301 report, several countries were cited for issues relating to the linkage of drug registration and patent status. Patent linkage is a controversial concept, which is considered inappropriate in many contexts, including in high-income countries such as in Europe, in part because of the extensive evidence of abuse, such as where weak or non-germane patents are asserted in the linkage process.

The May 10, 2007 Agreement made regulatory patent linkage optional rather than mandatory, a superior alternative to what the United States has proposed in the currently negotiated Trans-Pacific Partnership Agreement. The United States should not retreat from its May 10th deal and should not place countries on its Special 301 watchlists for choosing not to implement systems of patent linkage.

Exclusive Rights Over Test Data

We object to prior Special 301 reports, including the 2012 report, which have placed unilateral pressure on states to adopt TRIPS-plus measures on pharmaceutical test data. Exclusive rights over test data are designed to delay entry of generic medicines into the market and create requirements that generic competitors invest in unnecessary, unethical clinical trials if it wishes to register a drug before the exclusivity period ends. Exclusive rights are not required under TRIPS; international standards require only protection over such data, not exclusive rights. Other, more efficient and ethical models exist, such as cost-sharing models of protection, and have been implemented for test data over agricultural products.

Standards of Patentability

Another important flexibility under the TRIPS Agreement permits states to determine the appropriate standards of patentability, within the requirements of Article 27. The 2012 report suggested an effort by the United States to pressure states into granting patents, even where no increased efficacy is shown. These evergreening patents hinder generic entry into the market and USTR should not place countries on the Special 301 list for exercising this TRIPS flexibility.

Technological Protection Measures

Technological Protection Measures (TPMs) are not required by the TRIPS Agreement and the standards that the United States often pushes for with respect to TPMs where countries have adopted the WIPO Internet Treaties (the WCT and WPPT) go well beyond the requirements of international law. The WIPO Internet Treaties require the protection of TPMs only in connection with exercise of rights protected by copyright law and US efforts to adopt circumvention of a TPM as a separate, independent cause of action, such as its proposal in the Trans-Pacific Partnership Agreement, goes well beyond international requirements. The Special 301 report cited several TPPA negotiating partners, including Brunei, Chile, Mexico and Vietnam, as not implementing adequate measures to protect TPMs. There are numerous ways a state can implement its obligations under the WCT and WPPT, if it has acceded to and ratified these treaties, and the US model can be an inefficient and unfair system. The TPPA proposal is a controversial one, even within the United States, where the U.S. Court of Appeals Federal Circuit has considered that making the circumvention of a TPM a separate and independent cause of action to be an absurd result. The United States should not pressure countries to strengthen their anticircumvention measures or adopt standards that are not even uniformly applied within our own country.

Notice-and-Takedown

The United States notice-and-takedown procedure under the Digital Millennium Copyright Act (DMCA) has been heavily criticized and should not be exported to other countries, either through inclusion in free trade agreements or through pressure by USTR through its Special 301 process. In the United States, the notice-and-takedown system has been criticized because of abuses, including the negative impacts on free speech, flawed takedowns for non-infringing content, or inappropriate use targeted at a business competitor. Notices for takedown have increased exponentially over the last year and represent a costly and time-consuming process. Surveys of some small internet service providers reported tens of thousands of invalid or illegitimate notices. Because of the expense in evaluating notice claims, some internet service providers have stated a policy of taking down all content when receiving a notice in order to avoid any liability; such policies would certainly include the takedown of legitimate content.

Other processes for complying with the WIPO Internet Treaties exist and may prove to be better models than the DMCA. Alternative processes such as notice-and-notice systems, or procedures that require judicial oversight, promote fairness and safeguard against potential abuses by right holders. USTR should not place countries on the Special 301 list simply for failure to adopt the US-based, flawed system of notice-and-takedown.

Enforcement of Intellectual Property Rights

In the 2012 Special 301 Report, USTR placed several countries on its watch lists, at least in part for reasons relating to the enforcement of intellectual property rights. We note that many of these areas are controversial and go beyond the minimum standards of TRIPS, or in some cases, even beyond the higher standards contained in other agreements such as the Anti-Counterfeiting Trade Agreement (ACTA).

USTR urged countries, such as Canada, to provide customs officials with *ex officio* authority over importation, exportation and trans-shipment, despite the fact that such power is not mandated under TRIPS or other international obligations.

Additionally, the 2012 report encouraged statutory damages despite the fact that the Anti-Counterfeiting Trade Agreement (ACTA), an agreement primarily negotiated between high-income countries, rejected mandatory pre-established damages. ACTA made statutory damages one among other options, a clear signal that statutory damages have not been widely adopted internationally and often represent an inappropriate level of damages.

Conclusion

USTR should seriously question what the Special 301 report is intended to achieve and what value it provides. The Special 301 process unilaterally pressures countries to adopt TRIPS-plus measures which are often poor models for their domestic situations. The TRIPS-plus measures encouraged by USTR through both this Special 301 process and through free trade agreements, create patent and non-patent barriers, increase intellectual property rights without also ensuring proper balancing provisions, and negatively impacts public health, access to knowledge and human rights.