

The attached are KEI comments on the USTR Special 301 process were sent electronically via <http://www.regulations.gov>, for docket number USTR-2010-0037.

KEI comments on USTR 2011 Special 301 Review

February 15, 2011

KEI submits comments and requests the opportunity to testify at the March 2, 2011 hearing on the subject of the 2011 USTR Special 301 process (docket number USTR-2010-0037).

Introduction

In 2011, as for the last 21 years, the USTR will review and report the global state of intellectual property protection and enforcement pursuant to Section 182 of the Trade Act of 1974. For some of the countries included in the Priority Watch list, Watch list and Monitoring Section, this means not only a negative or at least diminished image of their country but also demonstrates the failure by the US to recognize some of the progress or concession they are making to comply with mostly US industries' demands and pressure. In many cases it also demonstrates how an unfair and non transparent process can be taking place year after year within the US government. While not widely commented on in the US press, the report has some negative effects on the perception of our country's foreign policies and its image. Because the Report mostly deals with health, knowledge, freedom and justice related issues, it should be produced in a transparent way and demonstrate a balanced, fair and evidenced-based examination and evaluation of the intellectual property enforcement mechanisms among our trading partners.

As stated in KEI's 2010 statement (<http://keionline.org/node/835>) to USTR, we were encouraged by the fact that in the last few years, some progress have been made and some of the demands by a narrow interest groups of lobbyists have not been mentioned or reflected in the USTR report itself. For examples, the 2010 report does not include "free software" nor words such as "textbooks or teaching materials" (in contrast to 301 reports in 2006, 2007 and 2008). There is no flat objection to compulsory licensing of patents on medical inventions¹, and the report refers many times to the Doha Declaration and the importance of access to medicines. However, the 2010 report could also be read as vague and thus confusing in some areas, and there is also evidence that in practice and often in private, U.S. Trade policies are more anti-consumer than was reflected in even the 2010 Special 301 Report.

Suggestions for the 2011 report

1. US policy on the protection of intellectual property rights should be consistent with other US policies and commitments, including for example the following global norms:

¹ USTR did mention it would monitor compulsory licensing of medical patents in Ecuador, and raised concerns about compulsory licensing of patents in China, including in the case of China, in the context of patents on standards.

- (a) The elements of the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) that address the importance of balance, national discretion in implementing global norms and the protection of consumer, social and public interests, including example, Articles 1, 6, 7, 8 and 40;
- (b) the 2001 WTO Doha Declaration on TRIPS and Public Health;
- (c) the 2008 World Health Organization (WHO) Global Strategy on Public Health, Innovation and Intellectual Property Rights (hereafter referred to as the Global Strategy), as set out in WHA61.21; and
- (d) the provisions of the World Intellectual Property Organization (WIPO) Development Agenda.
- (e) Article 7 of the Universal Declaration of Human Rights, which states:
 - 1. Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.
 - 2. Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.
- 2. The USTR must recognize the legitimacy of norms that protect consumers, promote freedom, and advance various social agendas. The 2011 Report should demonstrate understanding of the fact that the U.S. national interest is much broader than the concerns of some owners of intellectual property rights and includes issues of access to knowledge and health for the public at large.
 - (a) The United States has an interest in obtaining low cost medicines to address its global obligations to support treatments for HIV/AIDS and other diseases.
 - (b) The U.S. benefits from increased levels of education and health in developing countries.
 - (c) The U.S. globally shares access to published research that was funded by the NIH, and will benefit from expanded access to research funded by our trading partners.
 - (d) Millions of persons who live in the United States will benefit from expanded access to foreign collections of copyrighted works in accessible formats, and from the sharing of U.S. collections with persons with disabilities who live outside of the the United States.
 - (e) The U.S. has benefited more than any other country from the development of new information technologies, including those that depend upon considerable flexibilities

in copyright or patent laws.

3. In these and in many other areas, the U.S. national interest is not well defined by the asks and demands of the Pharmaceutical Research and Manufacturers of America (PhRMA), the Motion Picture Association of America (MPAA), the Recording Industry of Association of America (RIAA), the Association of American Publishers (AAP), or other right-owner groups who routinely lobby the USTR
4. The USTR should avoid using vague terminology such as "inadequate legal frame work" and use evidence provided by neutral parties.
5. The Report should not be used to pressure countries to adopt intellectual property protection that exceeds the level of protection existing in the US.
6. The Report is not the appropriate instrument to pressure countries into signing the WIPO Internet treaties or possibly the Anti-counterfeiting Trade Agreement.
7. USTR may want to more clearly separate issues relating to copyright, or trademark or involving patents and data. For example, in the case of Indonesia, one can read "Although enforcement efforts against pirated optical discs continue, the overall level of enforcement remains insufficient to address the country's major piracy and counterfeiting problem, including with respect to the counterfeiting of pharmaceutical products." (2010, pp26-27). Accumulating all these highly emotionally charged terms related to different policy fields in just one sentence is counter productive.
8. The Report should not address the normative issues of the term of protection for copyright and related rights. For example, Argentina is praised for some positive developments in 2009 that included "an increase in the term of protection for sound recordings and performances" (2010, p.24). In the view of many consumers, copyright experts, and US technology firms, shorter terms of protection are in the public interest, and enhance both consumer welfare and economic growth.
9. The Report should be clearer in areas that could affect education. For example, Argentina is praised for "an agreement with local universities to curb book piracy, and significant seizures of counterfeit goods by Customs." While USTR is appropriately concerned about commercial scale piracy of textbooks, it is important to note that many unauthorized uses of works are legal in the United States, particularly for purposes of education, under our system of robust limitations and exceptions to exclusive rights.
10. The report should avoid showing a vague understanding or even misunderstanding of foreign laws for both patents and copyright laws. For Chile, "it appears that the legislation fell short of fully addressing Chile's multilateral and bilateral commitments. For example, the legislation did not include protections against the circumvention of technological protection measures."(2010, p.25). However, Chile does protect TPMs in its general criminal and civil law code (19.223) and this is consistent with its obligations under the US-Chile FTA (art. 17.7.5) or the WIPO Internet treaties.

11. For India, we object to this reference in the 2010 report: "One concern in this regard is a provision in India's Patent Law that prohibits patents on certain chemical forms absent a showing of increased efficacy. While the full import of this provision remains unclear, it appears to limit the patentability of potentially beneficial innovations, such as temperature-stable forms of a drug or new means of drug delivery." (2010, p.24). India is a country with very low per capita incomes, and also a country that manufactures inexpensive generic medicines for much of the developing world. It is in our interest that India does not grant patents so liberally that it is difficult to manufacture generic medicines. We note further that USTR has singled out innovations relating to heat stabilized medicines, as something that India should patent. If you think for a minute about what the USTR is saying, it seems obvious that USTR opposes the supply of inexpensive generic medicines that can be used in areas without reliable refrigeration. This statement is particularly offensive, given the adverse health consequences of medicines that have been harmed due to poor storage conditions.
12. One trend in past 301 reports is to mix issues, types of intellectual property rights and to hype the consequences of infringement at the risk of losing credibility. For example, "Counterfeiting has evolved in recent years from a localized industry concentrated on copying high-end designer goods to a sophisticated global business involving the mass production and sale of a vast array of fake goods, including items such as counterfeit medicines, health care products, food and beverages, automobile and airplane parts, toothpaste, shampoos, razors, electronics, batteries, chemicals, and sporting goods." (2010, p. 9) and "It undermines key U.S. comparative advantages in innovation and creativity to the detriment of American businesses and workers. In its most pernicious forms it can also endanger the public. Counterfeiting of some products, such as automobile parts and medicines, poses a real risk to health and safety. Trade in counterfeit and pirated products often fuels cross-border organized criminal networks and hinders the sustainable economic development of many countries." (2010, p.5). The Report also alleges that the penalties are so low in many countries that they offer little or no deterrence (2010, p.10). It would be interesting to have evidence of existing punishment for infringement in the US and all its trading partners. One government official from a country on the priority list once asked: how many people are in jail for copyright infringement in the US? To be realistic about copyright piracy, one might also also inquire into the volume of unauthorized copies of copyrighted works in the United States, and the massive amount of patent infringement in the United States (including by many of the firms nominating countries to be included on the 301 list), to provide useful benchmarks for our trading partners.
13. The USTR should never place a country on the Special 301 list for having issued or threatening to issue a compulsory license on a medical technology, so long as the compulsory licensing is compliant with the WTO TRIPS Agreement.
14. The USTR should never place a developing country on the Special 301 list for a failure to grant exclusive rights to rely upon pharmaceutical test data to register a drug, when such a policy runs counter to the policy of promoting access to medicine for all.

This is relevant to the 2001 Doha Declaration on TRIPS and Public Health and WHA61.21. In this regard, the USTR needs to acknowledge the obvious, in all or nearly all developing country markets, the freedom to issue a compulsory licensing on a patent is meaningless in cases where the lawful sale of a product will be blocked by exclusive rights in test data. For this reason, every public health group that has been active in protecting the interests of poor people in developing countries has opposed the USTR policy to pushing for exclusive rights in pharmaceutical test data in developing countries. To the extent that the USTR believes there are legitimate trade interests involved, it has many alternatives to the use of exclusive rights, such as reasonable cost sharing, a practice actually used in the United States in cases involving chemicals that are used to protect crops. No intellectual property rights for data should be implemented without safeguards for public health, and the USTR should not demand such policies.

15. The USTR should reflect upon the meaning and consequences of element 6.2 (g) of the WHO Global Strategy (WHA61.21), as it concerns intellectual property for pharmaceutical test data and the ethical principals for clinical trials. Specifically, this element calls upon governments to:

promote ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki, and other appropriate texts, on ethical principles for medical research involving human subjects, including good clinical practice guidelines.

The Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects includes the following principle:

20. Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. 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. [Emphasis added]

One plain meaning of this provision is as follows. If a generic drug maker is required, in order to register a drug for sale, to replicate an experiment where there is already “conclusive proof of positive and beneficial results,” the generic drug company will be violating Article 20 of the Declaration of Helsinki. The remedy is not to prohibit a generic drug company from replicating the trial, but rather to eliminate the unethical requirement in the first place. The USTR Special 301 List cannot continue to demand that unethical policies be imposed by government regulators.

16. According to foreign government trade negotiators, the USTR is perceived as opposing a WIPO treaty for persons who are blind or who have other disabilities, on the grounds that such a treaty would set an unwelcome precedent in favor of consumer interests, and harm U.S. exporters of copyrighted works. KEI hopes these reports are wrong. In any event, the USTR should not in any way use its discretion to include a

country on the Special 301 list on the grounds that the government of that country supports new global norms to expand access to copyrighted works for persons who have disabilities.

17. The biggest challenge for USTR in terms of the enforcement of laws on copyright or patents is to improve the perception that such laws are reasonable and fair. To that end, national laws that provide for extensive exceptions and limitations to the exclusive rights of copyright or patent owners can be seen as a constructive development, in that they may improve the perception that the new norms should be respected by the public and enforced by governments and courts.

18. USTR should evaluate the benefits of a more balanced trade policy that encourages policies that expand access to knowledge, or the supply of knowledge as a global public good, when such policies enhance our welfare and national interest. In this respect, KEI would like to meet with the USTR to discuss, with other interested parties, the benefits of new global norms on access to government funded research, on possible strategies to move forward the various proposals for a biomedical R&D treaty, and on the proposal for a WTO agreement on the supply of public goods.

19. USTR should be more sensitive to the role that intellectual property rights can play as a barrier to legitimate competition, and as an enabler of unwanted protectionist activity. China and other countries have discussed the issue of patents on standards in the WTO Technical Barriers to Trade Committee, and KEI encourages the USTR to support more research on this topic.

20. KEI is concerned about reports that spurious assertions of copyright in pharmaceutical drug information (the information regulators require be provided to consumers) are being used to block legitimate trade in generic medicines.

21. There are many reports that countries have using complex court procedures to undermine efforts to invalidate poor quality patents, with the aim of protecting domestic markets from foreign imports.

22. The US and other countries are now struggling with solutions to the problem of inadequate access to orphaned copyrighted works. Some of the proposed solutions may involve limitations on remedies for the infringement of such works. This should not result in a country being placed on the 301 list.

23. The US now routinely considers allowing infringement of patents or copyrights, in cases where the continued infringement is in the public interest, and the right-holder receives a running royalty to compensate for the infringement. (Court cases following the law established in the *eBay Inc v. MercExchange, L.L.C.*, 547 U.S. 388 (2006)). This practice is permitted under the TRIPS agreement and ACTA, and not subject to the three step test for cases involving copyright. Other countries should be encourage to consider such practices.

24. The United States does not have a research exception for patents. In practice, infringement of patents is common during research. Lack of enforcement in this area, including via our publicly funded universities, is a good thing.

25. U.S. policy regarding the enforcement of copyrights or patents should be consistent with our policies regarding the importance of freedom of speech and freedom of information, and mindful of the relationship between surveillance of infringement and surveillance of speech.

26. USTR needs to develop a more clear policy statement on the relationship between copyright right enforcement and privacy.