

KEI comments on inconsistencies between USTR proposal for the TPPA and current US law

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As KEI has discussed previously, USTR's [proposal for the IP chapter](#) of the Trans-Pacific Partnership Agreement (TPPA) raises numerous concerns for [human rights](#), [access to medicines](#), and access to information, among other issues. Not only would USTR's proposal greatly impact those living in the countries of the TPPA negotiating partners--currently Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam--but many provisions of its February 10, 2011 text would be inconsistent with U.S. law, requiring changes to our domestic laws.

On Tuesday, KEI provided additional comments to USTR, several focusing on the inconsistencies between the leaked USTR's proposal on IPR and existing US legal norms and legislative proposals.

Copyright:

- USTR's proposal would give copyright holders the right to prohibit importation of their works, effectively banning parallel importation despite the fact that this is an unsettled area of US law.
- The provisions related to technological protection measures (TPM) would create a separate cause of action for circumvention of a TPM from any underlying copyright infringement.
- Civil remedies under the USTR proposal for violations of TPM provisions goes beyond what is required under the DMCA
- Limitations and exceptions to the TPM provisions are potentially drawn more narrowly and may make new exceptions more difficult to obtain

Patents:

- USTR would require the granting and enforcement of surgical methods. In the US, we do not enforce these patents against medical practitioners, and the TRIPS permits its members to eliminate patents on "diagnostic, therapeutic and surgical methods for the treatment of humans or animals."

- The USTR proposal requires patents be granted on "any new forms, uses, or methods of using a known product" even where there is no enhancement of the efficacy of the product. This is bad public policy, and would change US legal norms for granting patents.

Data Protection:

- The term for data protection for pharmaceutical products is an area that is not well settled in the US. President Obama's 2012 budget proposal requests seven years of protection for biologic products, while some members of congress are pushing for twelve years of protection for biologic products in the TPPA. USTR has not indicated if it will retain the flexibilities of the May 10, 2007 agreement as regard test data protection.

Civil Enforcement:

- Depending on the manner in which the provisions are read, USTR potentially ignores the large number of provisions in US law which eliminate the possibility of injunctions, even in cases of infringement
- USTR's aggressive damage provisions provide for measures leading to higher damages and fail to take into account the numerous limitations on damages currently provided for by US law
- The provisions would presume attorney's fees in trademark cases, flipping the current presumption

Border Measures:

- Depending on the way USTR's proposal is read, the TPPA could limit the ability of the US Government to import goods that are infringing

Enforcement in the Digital Environment:

- USTR would expand the definition of "service provider," thereby expanding liability
- The TPPA proposal fails to incorporate important privacy safeguards which are contained in the DMCA

Pharmaceutical Pricing:

- Concerns exist regarding whether USTR's proposal may impact US drug reimbursement programs

Areas Potentially Impeding Legislative Reform Efforts:

- The need to address the problem of orphan works is widely recognized and the TPPA language fails to include limitations on damages for cases involving orphan works
- We have concerns that USTR's proposal may limit reform in the area of data protection for pharmaceutical products such as the bill introduced in 2010 that would eliminate exclusive rights on test data where such repetition would violate medical ethics

Considering the large number of inconsistencies between the US proposal for the TPPA and current US law, USTR's decision to keep these texts secret is inexcusable. We note that USTR proposed several provisions in ACTA that were similarly inconsistent with US law and prompted Senator Wyden to request the an [analysis of these inconsistencies](#) from the Congressional Research Service. KEI's April 2010 research note on ACTA and inconsistencies with US law as they relate to injunctions and damages is [available here](#). The fact that many of these mistakes are replicated in the TPPA is highly concerning and given the impact that the proposals, if accepted, will have on our domestic law, we urge USTR to make these documents public.

As we have noted previously, the lack of access to information also quite unequal as some corporate interests have special access to information about the negotiations not made available to the general public. Industry representatives who sit on Industry Trade Advisory Committees (ITAC) such as the ITAC on Intellectual Property Rights or ITAC on Chemical, Pharmaceuticals, Health Science Products and Services, for example, are heavily represented by large private trade associations and pharmaceutical companies. This set up allows industry to have greater access to information and shape the negotiating positions to conform to their private interests while the general public is not afforded the same opportunities.

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