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Dear Members of the Committee on Legal Affairs,

Public Citizen is a non-profit consumer advocacy organization founded in 1971 and based in Washington, D.C. We have over 225,000 members and supporters. Areas of organizational focus include, among others, consumer protection, drug safety, trade and global access to medicines.

We have previously raised concerns that the purported benefits of the Anti-Counterfeiting Trade Agreement (ACTA) for public safety would be slim at best.[1] Meanwhile, ACTA's opportunity cost for more effective measures against unsafe products could be significant. Further, ACTA may impose direct costs on public health, by creating uncertainty and financial disincentives for the shipping of generic medicines.

We strongly advise a deeper and more considered legal review of ACTA. Among other topics, this review must assess:

- The consequences of authorizing special and ex officio border measures in cases of alleged or suspected civil trademark infringement. These cases of "similar" marks do not involve counterfeiting or criminal conduct. They are cases typically resolved through complex legal analysis in courts. The parties are typically legitimate businesses that can be served with legal process. Special, preemptive border measures for civil trademark cases create special concerns for generic medicines, which sometimes bear similar packaging due to the importance of communicating bioequivalence. Indeed, courts have narrowed trademark and trade dress protection for pharmaceuticals due specifically to the consumer benefits of similar packaging. Applying ACTA's special border measures to suspected civil trademark infringement jeopardizes generic competition with no benefit to public safety.

- Whether ACTA's approach assigning law enforcement (customs authorities) to intervene in civil disputes and suspected civil infringements before judicial process (as with special border measures) violates standards of civil legal process.

- ACTA's strange concept of non-discrimination between intellectual property rights, articulated in the border measures chapter (Article 13). Patents, trademarks, copyrights, geographical indications etc. are indeed separate and discrete rights, each with its own separate appropriate standards for infringement, remedies, etc. The very concept of distinct commercial rights requires discrimination between them. What are the consequences for the legal traditions of patents, copyrights and trademarks of establishing standards against discrimination between them?

- The legal uncertainty created by this principle of non-discrimination in special border measures. How are the Parties to determine which standards do or do not "discriminate unjustifiably between intellectual property rights"?

- The capacity of customs officials to properly and accurately apply special border measures outside the context of criminal activity, e.g. willful trademark counterfeiting and copyright piracy on a commercial

[1] *See e.g.* Maybarduk, Peter. 2010. ACTA and Public Health. PIJIP Research Paper No. 9. American University Washington College of Law, Washington, DC, available at: http://digitalcommons.wcl.american.edu/research/9/.

scale. Customs officials are not competent to assess infringement of the various discrete intellectual property rights. For instance, civil trademark infringement requires surprisingly complex legal analysis, often including multi-factor tests and market-specific knowledge, and is frequently the subject of lengthy and considered litigation at court.

- What new legal authority ACTA provides to protect consumers from unsafe products, that is not already provided for in regulatory authority or could not be more comprehensively provided by regulatory authority in cooperation with law enforcement. For example, in the area of pharmaceuticals, we know that drug regulatory authority and cooperation with law enforcement in the United States already provide border measures against counterfeit marks and also against falsified medicines that do not infringe trademarks (something ACTA cannot do), and accomplish each without raising the same concerns for legitimate generic products that ACTA's approach has raised since its first draft. A comprehensive regulatory framework better protects the public, without ACTA's risks. Given the opportunity cost in approaching “anti-counterfeiting” through a sole yet expansive intellectual property rights framework, we contend that ACTA's health and safety costs significantly outweigh its benefits.

- To what extent ACTA produces overlapping or competing institutions for influence over international intellectual property enforcement norms and dispute resolution. The ACTA Committee, together with ACTA’s Article 38 consultations procedure, provides a new multilateral forum for discussing norms and disputes that in many cases could also be brought before either the World Intellectual Property Organization (WIPO) or the World Trade Organization (WTO). While ACTA states that consultations will be undertaken “without prejudice” to WTO dispute resolution, ACTA nevertheless establishes a new multilateral forum of limited membership and new rules, and would seem to necessarily derogate the influence of WIPO and WTO in this regard.

For a more detailed discussion of some of these issues, please consult the article referenced in note 1. Please feel free to contact us with questions.

Sincerely,

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