



Innovation & Technology Policy Lab
at **Duke** UNIVERSITY
Collaboration Across Borders

May 20, 2015

Alexander Macgillivray & Nancy Weiss
Office of Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, DC 20504

Dear Mr. Macgillivray and Ms. Weiss,

The Innovation and Technology Policy Lab at Duke University is interested in the practical impact that policy has on global access to technological innovations. Our experience in this field leads us to be concerned about some of the Intellectual Property (IP) provisions proposed in the Trans-Pacific Partnership Agreement (TPP).

Specifically, the WTO TRIPS Agreement contains important exemptions to the requirement that patents be granted on inventions, including drugs and medical devices. Together, Articles 30 and 31 of TRIPS allow for exceptions to patent monopolies under different situations; Article 30 allows a monopoly exception when the “three-step test” is passed, and use of Article 31 typically results in issuance of a compulsory license. The range of justifications and procedures provided for in these two Articles are important components for addressing abuses of monopoly rights, research exemptions, government use, and other issues of access. For example, governments have been able to reduce to price of essential HIV/AIDS medications and vastly expand patient coverage using the measures provided for by TRIPS.

As of the May 16, 2014 draft of the TPP, these important TRIPS provisions are dangerously limited and the risk this poses to public health should not be underestimated. The Article 30 exceptions are subject to Investor-state Dispute Settlement, and language protecting the Article 31 exceptions has been removed. The TPP draft resulting from the Ho Chi Minh Round vastly limits the use of compulsory licenses and makes it so that any use of remaining exceptions carries the risk of international arbitration. Among other things, these barriers greatly limit policy space available under TRIPS to prevent or correct the excessive costs of medicines.

Furthermore, the recent drafts of the TPP contain broad requirements for the payment of damages for patent infringement. As of May 16, 2014 it reads:

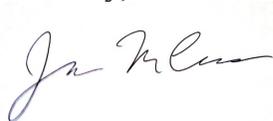
“[The TPP member’s] judicial authorities shall have the authority to consider, inter alia, any legitimate measure of value the right holder submits, which may include lost profits, the value of the infringed goods or service measured by the market price, or the suggested retail price.”

Not only is this text inconsistent with the United States' own position on the payment of remedies for patent infringement, but it also poses a threat to global health. Among other examples, the Affordable Care Act contains limitations on damages for biologic drug patents that would fail to meet the TPP standards. The ACA states that payment of a "reasonable royalty" should be the "sole and exclusive remedy" in cases of infringement. The current liability rules in U.S. law, seen in 35 U.S.C. §271(e)(6)(B), are designed to encourage full and transparent disclosure of biologic drugs during patent application and ensure production knowledge is available to potential competitors. The ability of biosimilar manufacturers to produce competitor products is important when considering product pricing and access to medicines. However, limiting liability rules to the standard contained in the TPP also threatens important safeguards and strategies for access across patents, trademarks, copyrights, and other forms of IP rights.

The contradiction between US law and the norms contained in the TPP opens up risk of investor-state litigation. Ultimately, passage of the TPP would decrease state sovereign immunity. For example, after the precedent set by the U.S. Supreme Court in *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank et al.* (98531) 527 U.S. 627 (1999), Argued April 20, 1999–Decided June 23, 1999, state governments can decide their own remedies for IPR infringement. This power is currently coming under the spotlight as the Department of Veteran's Affairs is asking for the use of 28 U.S.C. §1498 in order to be able to treat Hepatitis C Virus. The retail price suggested by Gilead is \$95,000 per patient and the Veteran's Affairs budget is unable to provide treatment at this price. 28 U.S.C. §1498 is supposed to allow governments use of a patented product with the payment of a reasonable royalty, but under the norms of the TPP, Gilead could ask for compensation equal to \$95,000 per patient and deter the government from taking action to treat its veterans.

When considering the problematic aspects of the TPP discussed above, it is our hope that the OSTP will keep in mind the obligations the US has under the WTO Doha Declaration on TRIPS and Public Health. The Obama Administration should recognize the detrimental effect that the TPP IP Chapter could have on global health and governments' ability to ensure access to medicines. The trade negotiations around the TPP will have a global impact, and it is of the utmost importance that damaging IP legislation concerning patent exemptions and liability rules are removed from the Agreement.

Sincerely,



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