US Doha flexibilities in its proposed TPP IP text are not nearly good enough

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The U.S. pays lip service to the Doha Declaration on the TRIPS Agreement and Public Health in both Article [X] and Article 9.3 of its leaked September 2011 Trans-Pactific Partnership Intellectual Property Rights Chapter (selected provisions), but close analysis proves that the words chosen do not provide sufficient guarantees to assure that TPPA partners will be able to make maximum use of TRIPS and Doha compliant flexibilities to maximize access to more affordable medicines for all.

Art. [X] 1. starts with the now standard affirmance of the Parties' prior commitment to the Doha Declaration. Although it is boilerplate to acknowledge a unanimous WTO commitment made nearly ten years ago and although acknowledgement is superior to exclusion or rejection, the boilerplate does not make up for an absence of specific clarifying commitments about how countries can operationalize Doha to overcome the many TRIPS-plus provisions in the TPPA proposal.

Art. [X] 2. then articulate "understandings" in the U.S. unilateral TPP IP proposal. Subsection (a) states that "The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency." The U.S. has chosen its language carefully to suggest that TRIPS and Doha flexibilities are not available for all medical needs and conditions, but are instead limited to the acknowledged public health emergencies of HIV/AIDS, TB, and malaria (and perhaps a subset of other infectious disease epidemics) and to a narrow subset of public health needs that can be classified as matters of extreme urgency or national emergency. However, the burden of non-communicable chronic diseases is escalating throughout the world, but particularly in low- and middle-income countries where the cost of many chronic disease medicines, including those for cancers, psychiatric illnesses, other illnesses, is much too expensive for individual patients, insurers, and governments. Likewise, many developing countries face a persistent crisis with respect to neglected tropical diseases where newer, more

expensive medicines might again be priced at unaffordable levels. The U.S.'s intent to purposefully exclude non-infectious chronic disease can be inferred from its persistent efforts at the UN High Level Meeting on NCDs to ensure that they were not described as an "epidemic" nor as an "emergency." Subsection (a) ends with Doha-consistent boilerplate that the "Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all."

Art. [X] 2.(b), next tries to squeeze the interpretation of TRIPS and Doha compliant compulsory licenses into the narrow and procedurally labyrinth contours of the so-called TRIPS/Health solution. Paragraph 6 of the Doha Declaration required the development of a quick and expeditious mechanism allowing export/import of medicines to countries that had insufficient pharmaceutical capacity locally to either produce medicines that were not patented or those authorized pursuant to a properly issued compulsory license or government use order. Article 31(f) of the TRIPS Agreement had created a major barrier for these non-producing importers because it restricted the quantity of medicines produced pursuant to a compulsory license that could be exported to other countries to "non-predominant" amounts, presumably less than 50% of output. Unfortunately, the TRIPS/Health solution that was adopted is painfully complex and has only been used once in eight years by a generic company, Apotex, that says it will never use it again unless the procedures are simplified. Countries should maintain flexibilities to exploring and using other options instead being tricked into thinking that the TRIPS/health solution is adequate or that it is the only importing option for non-producing countries. Other available solutions include: (1) export of unlimited quantities where a compulsory license is issued on competition ground (Art. 31(k), (2) non-predominant quantities pursuant to an ordinary Art. 31 licenses, or even (3) export to non-producing countries through an easy-to-use Art. 30 limited exception.

Article 9.3, which deals with "measures relating to certain regulated products" and more particularly with U.S. proposals for data exclusivity and patent-registration linkage, also contains boilerplate references to the Doha Declaration. It reiterates that "a Party may take measures to protect public health in accordance with" the Doha Declaration, any current waiver (including presumably the TRIPS/Health solution) and any eventual amendment based on implementing the Doha Declaration (presumably referring indirectly to proposed amended Art. 31bis. This boilerplate provision in the "data exclusivity/patent linkage" portion of the TPP IP text is particularly disappointing because it fails to specify concretely that governments can act to override data exclusivity and

patent/registration linkage either (1) to ensure rights to obtain marketing approval when a compulsory license or government use license is issued or (2) to have a compulsory-license like exception to data exclusivity and patent/registration linkage even if no patent bar is in place. The 2007 New Trade Policy adopted by the US Congress during the Bush administration, which led to revisions in the US/Peru and US/Columbia free trade agreements, provided express guidance on how to operationalize a public health exception to data exclusivity and patent/registration linkage which is lacking from the current proposal.

However, an even larger problem exists with respect to the US TPPA IP proposal and the alleged protections of the Doha Declaration. The proposed text contains many explicit TRIPS-plus IP provisions including: (1) lowered patent standards, presumptions of valid patent status, and express obligations to grant patents for new uses and new forms of existing products), (2) elimination of rights of pre-grant opposition, (3) extension of patent terms beyond the TRIPS requirement of 20 years to compensate for delays in granting patents and/or in granting marketing approval, (4) five-year data exclusivity following the first registration of a new pharmaceutical product with rights to evergreen data exclusivity for an additional three years whenever new clinical trial data is submitted, (5) mandatory patent/registration linkage giving patent holders a right to prevent registration of alleged patent infringing products no matter how weak the patent claim is, (6) unconscionable restrictions on government price control and therapeutic formulary policies, and (7) multiple TRIPS-plus enforcement measures. In each instance, these textually specific TRIPS-plus provisions might not be reversible merely because of rights to "interpret" TPP provisions in light of the Doha Declaration. Even though Parties will retain rights in implementation and interpretation and should be urged to exercise them, directive language and heightened, deepened, and extended IP rights might impede their implementation and interpretive flexibility.

A better text would make clear that no TRIPS-plus provision is enforceable if a country has a legitimate public interest need. Such a provision is particularly important to the developing countries that are involved in these negotiations. Better yet, negotiating partners should band together to resist the myriad TRIPS-plus IP provisions proposed in the leaked US IP chapter. The best interpretation of the Doha Declaration is that it prevents the proposal or adoption of TRIPS-plus measures that have any potential of negatively impacting public health and access to medicines for all.

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