

Steps USTR Can Take to Address Key Concerns in IP-Health Platform

1. Reverse the trend towards more TRIPS-Plus intellectual property (IP) rules, and stop retaliating against countries for not adopting TRIPS-Plus rules or using TRIPS safeguards and flexibilities. Instead, publicly encourage and promote countries' efforts to increase access to medicines through their adoption of flexibilities described in the Doha Declaration on the TRIPS Agreement and Public Health.

- 1.1 Retroactively apply the IP provisions in the May 10, 2007 New Trade Policy for America to all FTAs signed by the US since 1994, and ensure that all current and future bilateral and regional negotiations, such as the Trans-Pacific Partnership, at a minimum do not include stricter IP provisions for pharmaceuticals than those in the May 10, 2007 agreement. This agreement made both linkage and patent term extensions optional, and limited the negative consequences of data exclusivity on access to medicines, but it unfortunately still permits some TRIPS-Plus measures that could impede access to medicines and should therefore be modified accordingly in the future.
- 1.2 Initiate an urgent, comprehensive review of USTR interpretations of minimal obligations of key TRIPS provisions affecting pharmaceuticals. The review should include an evaluation of how TRIPS-Plus IP protections, such as data exclusivity, can adversely affect access to medicines. It should also include opportunities for public comment, discussion and reply to the various proposals put forward so that all relevant stakeholders can contribute, and the widest possible array of information is considered, before the review is complete. Until the review is complete, refrain from implementing or enforcing TRIPS-Plus IP measures in trade agreements, Special 301 Reports, trade missions, technical assistance, or other initiatives.
- 1.3 Stop all retaliatory action or pressure against countries that enact or use TRIPS- and Doha-compliant measures to increase access to more affordable medicines. Thus, for example:
 - 1.3.1. Stop listing countries in its Special 301 Report for issuing TRIPS-compliant compulsory licenses (i.e., Thailand); for allowing parallel importation; for adopting stringent standards for patentability of medicines and allowing pre-grant opposition procedures (i.e., India); or adopting data protection but rejecting data exclusivity and patent/registration linkage.
 - 1.3.2. Do not conduct or allow formal or informal discussions between US officials and trading partners in which partners are asked to refrain from or alter TRIPS-compliant conduct such as using TRIPS flexibilities to promote access to medicines.
 - 1.3.3. Stop imposing Generalized System of Preferences (GSP) sanctions in retaliation for utilization of TRIPS flexibilities.
 - 1.3.4. Stop imposing TRIPS-Plus measures in WTO accession agreements.

2. Stop pursuit of enforcement measures that exceed TRIPS standards and ensure that pursuit of an IP-based anti-counterfeiting agenda does not adversely affect access to medicines.

- 2.1 Stop pursuit of enhanced non-private enforcement measures that exceed TRIPS standards, such as those that increase criminal enforcement and impose high burdens on developing countries. In particular, avoid such enforcement rules that can adversely affect access to generic medicines – for example, mandatory injunctions in lieu of damages, seizures of goods-in-transit, and criminal prosecutions of patent violations.
- 2.2 In ongoing negotiations on the Anti-Counterfeiting Trade Agreement (ACTA) and other anti-counterfeiting negotiations and activities in forums like WHO and World Customs Organization, ensure that the US position respects the legitimacy of generic medicines and clearly

distinguishes generic equivalents from counterfeit medicines, which are fake medicines produced without government regulation or control for safety and efficacy and which willfully violate trademarks. Otherwise, ACTA and other anti-counterfeiting initiatives would become one more tool to extend TRIPS-Plus IP rules and limit generic competition.

3. Reform the Special 301 Report process

- 3.1 Refrain from using the Special 301 Report to intimidate countries for manufacturing generics or arranging to procure lower price medicines. For example, the 2009 report noted concern with the “unauthorized use of bulk active pharmaceutical ingredients” by manufacturers in Brazil, China, and India, all of which are important suppliers of generics to the world’s poor. The report also notes concern with Thailand’s recent compulsory licenses on medicines, which the Thai Health Ministry says enabled the expansion of antiretroviral treatment to 30,000 more people with HIV/AIDS, and which help the government provide healthcare to people with cancer and heart disease.
- 3.2 Do not use the Special 301 Report to push for TRIPS-Plus IP legislation or for TRIPS-Plus enforcement of IP. Eighteen countries are cited for not providing adequate protection of test data or linkage between patent and health authorities in the 2009 report. While TRIPS does call for test data to be protected, the five-year (or longer) periods of exclusivity commonly included in FTAs and consistently sought by the pharmaceutical industry exceed TRIPS requirements and limit access to affordable medicines. Linkage between patent and health authorities is also outside the scope of the TRIPS agreement and limits generic competition.
- 3.3 Increase the procedural fairness of the Special 301 process. This should include permitting countries an opportunity to reply to industry proposals for listing, including comments on any data presented in industry submissions to USTR.
- 3.4 Review and evaluate the compatibility of the Special 301 program with the WTO mandate for multilateral dispute resolution, and the appropriateness of unilateral action against countries that meet their TRIPS obligations.

4. Promote new thinking on incentive mechanisms for innovation to develop needs-driven health products without depending on high monopoly prices and limiting affordable access.

- 4.1 As part of the US government inter-agency review process of innovation policy, encourage, support, allow and undertake, as appropriate, the following actions:
 - 4.1.1 Full implementation of the World Health Assembly resolution 61.21, which contains a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. This includes ensuring that the WHO is given the mandate to implement the entire policy agenda, as well as sufficient financial and human resources to carry it out.
 - 4.1.2 The use of diverse mechanisms that separate research and development (R&D) incentives from prices, for example through the use of innovation inducement prizes that reward innovations that improve health outcomes and permit open competition for products. The prize mechanisms should also be designed to encourage sharing knowledge, data, materials and technology. In the coming months, the WHO Expert Working Group on R&D financing plans to discuss proposals presented by developing

countries like Bolivia, Barbados, Suriname and Bangladesh. These proposals should be seriously considered.

- 4.1.3 The initiation of discussions on a WHO biomedical R&D treaty, ensuring WHO is included as a key stakeholder in these discussions. The importance of such a treaty was agreed by all WHO Member States in the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. A biomedical treaty should provide the mechanisms to ensure sustainable finances for needs-driven R&D and set global norms in other areas, such as access to government-funded research through open access to scientific articles, basic research, technology and data.
- 4.1.4 The licensing of all publicly funded US biomedical R&D to the developing world, for example by licensing to the UNITAID patent pool publicly-funded IP held by NIH and Universities, and by supporting similar initiatives addressing other health needs, to ensure affordable upstream and downstream access to medical technologies relevant to health needs of developing countries.
- 4.2 In order to better inform the USTR's position on these and other issues, organize a series of public events where a diverse range of stakeholders can present their proposals. Discussions should include innovation inducement prizes that reward improvements in health outcomes and require open licensing, the use of health-related patent pools, and proposed elements of a WHO biomedical R&D treaty.

5. Enable fair drug pricing and reimbursement policies

- 5.1 Do not seek, through FTA negotiations or through consultations with our trading partners, any restrictions on the use of evidence-based pricing and reimbursement policies. Countries should be entitled to develop therapeutic formularies, public and private reimbursement schemes, reference pricing, and other evidence-based regulatory controls on pricing and reimbursement.

6. Increase transparency and accountability of the process of trade policy development

- 6.1 Cooperate with Congress' review of the trade advisory committee process, and the creation of a Tier 2 Public Health Advisory Committee on Trade (PHACT).
- 6.2 Appoint a sufficient number of qualified, independent public health representatives to all levels of trade advisory committees to assure a fair balance of views on the committees.
- 6.3 Consult with a wide range of public stakeholders on broader measures to increase transparency.