Public Written Submission on Joint Strategic Plan for Federal Effort against Intellectual Property Infringement

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Oxfam America is an international development and humanitarian relief agency working for lasting solutions to poverty and social injustice. We are part of a confederation of 14 Oxfam organizations working together in over 100 countries around the globe.

Oxfam America's submission is focused upon our concern that a new intellectual property enforcement strategy could adversely affect access to affordable medicines in developing countries. Ensuring access to affordable medicines is a core element of the human right to health. Yet over two billion people still lack regular access to affordable medicines, due in part to the high price of existing medicines. Strict intellectual property (IP) protection strengthens monopolies and restricts generic competition, which leads to higher medicine prices that are unaffordable for most people in developing countries.

Discussion

1. **Intellectual property obligations should be left to each country to enforce according to its own rules, procedures and processes.**

Article 1(1) of the TRIPS Agreement states: "Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice." Patent holders of pharmaceutical medicines should be provided all legal avenues available under the law of each WTO Member State to pursue patent protection for medicines.

The United States should not interfere with the sovereign right of each developing country to determine how it will enforce its intellectual property laws, particularly for pharmaceuticals. Advice, assistance and pressure by developed countries, especially the United States, are too often used to restrict the ability of developing countries to use flexibilities under TRIPS to promote and protect public health (e.g., compulsory licensing and parallel imports), as well as to prevent ever-greening – despite increased recognition in many developed countries that ever-greening and abuse of the patent system is rampant amongst drug companies.

Instead of improving the functioning of patent offices to independently assess patents according to a country's own laws, assistance is often used to pressure developing countries to modify substantive law that determines whether or not a patent should be granted. This can have serious consequences for access to medicines, as granting additional patents that are frivolous and do not promote innovation delays generic competition beyond twenty years. Undue influence by the United States and other countries can also hinder the ability of developing countries to exercise full use of public health safeguards. Patent offices in many developing countries have a role to play in enforcing TRIPS flexibilities. Undue influence by the United States can prevent developing countries from taking responsible steps to protect the health and well-being of their population.

2. **U.S. strategies to enhance intellectual property enforcement should under no circumstance impair the full use of and adherence to the Doha Declaration on TRIPS and Public Health in developing countries.**

All WTO Members, including the United States, agreed to the Doha Declaration on TRIPS and Public Health, which states:

> We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

Measures to enhance intellectual property enforcement should not impair the full use of the Doha Declaration on TRIPS and Public Health. Measures taken by developing countries to promote public health under each country's intellectual property code have been severely criticized by the United States as measures that 'steal the intellectual property' of rights holders. Yet enforcement of intellectual property on behalf of rights holders under no circumstance abridges the right of developing countries under TRIPS to use safeguards and flexibilities to protect public health. Any demand to the contrary by the United States is inconsistent with both TRIPS and the Doha Declaration. Intellectual property enforcement should only be concerned with ensuring that all forms of intellectual property, which countries are obligated to protect under the TRIPS Agreement, are given protection subject to the limitations, exceptions and flexibilities available under TRIPS.

3. **Customs and border officials should play no role in determining whether a medicine infringes a patent. This especially includes medicines-in-transit.**

Customs and border officials should play no role in ascertaining the patent status of a medicine, either on an ex officio basis or at the behest of a pharmaceutical company. In the first place, customs and border officials do not have the necessary information that would enable them to make such a determination objectively. Secondly, many customs and border officials do not have the analytic capacity that either judges or patent examiners have to make such determinations. Patent infringement, especially in the field of pharmaceutical technology, is a technical and complex analytical process that requires considerable scientific and legal expertise. Thirdly, it is inappropriate for any Government to enforce the patent rights of one party in a manner that could limit or restrict the ability of another party to challenge the claimed patent. Governments should act as arbiters between private parties that contest whether or not a product or process of one party infringes on the patent of another private party. By requiring customs and border officials to enforce intellectual property on behalf of a patent holder, in lieu of leaving the responsibility to the patent holder to enforce its rights in a court of law, a Government will prejudice the protection of intellectual property and disturb the

careful balance between protection of intellectual property and promotion of the public interest (and competition). In fields of technology such as medicines, directing State resources towards enforcing intellectual property can discourage generics companies from challenging frivolous patents and promoting generic competition, which harms competition and the public interest.

Customs officials should play no role in enforcing patents or in making patent determinations that can limit the movements of goods-in-transit. This can have serious public health consequences when applied to pharmaceutical products, and has been particularly apparent across the European Union (EU). Since late 2008, customs officials in the Netherlands, Germany and France have seized at least 20 shipments of legitimate generic medicines. Of the shipments, 19 were legally manufactured and exported from India and intended for developing countries where they could be legally imported. Patents did not exist on the medicines in either the country of origin or destination. These shipments were seized as a result of national implementation of an EU regulation that empowers border officials to classify and seize medicines as counterfeits if the customs official determines (often at the direction of pharmaceutical companies) that the medicines violate territorial patents of the relevant EU country. The IP standards of the EU countries have been applied to medicines in-transit even though these medicines are not intended for domestic consumption in the EU. Medicines that were seized included a cardiovascular disease medicine (Losartan) intended for Brazil, and a key anti-retroviral medicine, (Abacavir), purchased by the Clinton Foundation and intended for Nigeria. Under no circumstance should the United States seek to put in place similar regulations.

4. **Border determinations of patent status play no role in curbing counterfeiting and do not improve the safety and efficacy of medicines.**

Counterfeit medicines are medicines that willfully infringe a trademark. The patent status of a medicine bears no relationship as to whether or not a medicine is counterfeit. This is broadly recognized, including under the TRIPS Agreement. Pursuant to Footnote 14 of Article 51 of the TRIPS Agreement, a counterfeit product is defined as follows:

> "For the purposes of this Agreement: (a) 'counterfeit trademark goods' shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;"

Determination of patent status of a medicine at a border, whether the product is entering the country or is in-transit, does nothing beyond other measures already in place to curb counterfeiting. On the other hand, border measures that limit the trade in legal generic medicines can have the opposite effect. By increasing medicine prices, especially in poor

countries, this can drive patients to purchase counterfeit products – which are the only medicines they can afford.

Furthermore, while curbing counterfeit medicines can assist in reducing the movement of fake products, curbing counterfeit medicines does not address the broader concerns around the proliferation of substandard medicines, or medicines that are inadequate due to poor quality and safety. Substandard medicines can be branded or generic medicines; they are medicines that often do not provide pharmacological benefits due to inadequacies in the manufacturing process. Counterfeits are only a subset of substandard medicines. The problem of substandard medicines requires a range of interventions that are distinct from those used to curb counterfeiting. In particular, it is essential that countries apply a public health framework to curb substandard medicines – including increased pharmaco-vigilance, enhanced support to drug regulatory authorities, broader prequalification of medicines – including at the World Health Organization – and investments to improve the manufacturing practices of manufacturers.

In sum, the patent status of a medicine bears no relationship as to whether the medicine is substandard. The quality and safety of a medicine is not tied to whether the product does or does not infringe a patent. Substandard products can be branded or generic; reducing substandard medicines requires better manufacturing practices and oversight of manufacturing, not increased patent protection.