Oxfam New Zealand

Submission to the Ministry of Economic Development on the Anti-Counterfeiting Trade Agreement (ACTA)

Summary of Recommendations

1. Negotiators must make a commitment to full transparency, with a defined timetable to release the negotiating text to broader public scrutiny.

2. The scope of ACTA exceeds the relevant intellectual property rights pertaining to counterfeit products. Patents must be excluded from ACTA, and trademark-based interventions must be limited to ensure there is no harm to the public interest.

3. Border measures and new criminal enforcement penalties present a particular threat to access to medicines and must be circumscribed.

4. Any powers granted to a new 'ACTA Secretariat' must be limited in nature, and should not exceed or replace any authority already granted to the World Trade Organisation and World Intellectual Property Organisation, and developing countries should not be required to sign up to ACTA provisions as part of trade negotiations. All non-governmental organisations should be given full opportunity to engage with the ACTA Secretariat and to observe and participate in subsequent discussions.

Introduction

Oxfam New Zealand appreciates the opportunity to submit written comments in advance of the upcoming negotiating round of the Anti-Counterfeiting Trade Agreement (ACTA).

Oxfam New Zealand 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 organisations working together in over 100 countries around the globe. Oxfam believes that trade can be an engine for development and poverty reduction as long as the rules of trade work to benefit poor people and developing countries. Well-managed trade has the potential to lift millions of people out of poverty. To achieve such a goal, trade agreements, which set the rules for ongoing trade relations, need to work to improve livelihoods and reduce poverty in developing countries.

Previously, Oxfam New Zealand has not submitted comments to the Government on ACTA. Thus, our comments discuss a broad range of on-going concerns with ACTA and the negative impacts the Agreement could have upon poverty reduction in developing countries.

Background

Oxfam is concerned that the Anti-Counterfeiting Trade Agreement will adversely affect access to affordable medicines and that this will cost lives.

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 and the lack of new medicines needed to treat diseases that disproportionately affect poor people in developing countries. 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. In 2001, all World Trade Organisation (WTO) members adopted the Doha Declaration on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health, which reaffirmed the primacy of public health over the protection of intellectual property for medicines.

Unless negotiators ensure the protection of public health, ACTA will ignore the obligations of the negotiating parties to uphold the Doha Declaration on TRIPS and Public Health. Oxfam has numerous concerns with ACTA and believes that the Government of New Zealand must argue for the following measures during this upcoming round of negotiations.

1. **Negotiators must make a commitment to full transparency, with a defined timetable to release the negotiating text for broader public scrutiny.**

Oxfam is disappointed that negotiators have failed to establish a clear plan to release the negotiating text for broader discussion. General consultations, leaks and broad outlines of principles are wholly insufficient to ensure adequate scrutiny – particularly given the Agreement's complexity. We are encouraged that nearly all negotiating parties have expressed a preference for greater transparency, including a recent announcement by the European Commission that it would seek full disclosure of the ACTA text during the New Zealand negotiating round. Our hope is that the Government of New Zealand, as hosts of this negotiating round, will ensure that full transparency is achieved.

2. **The scope of the Agreement exceeds the relevant intellectual property rights pertaining to counterfeit products. Patents must be excluded from ACTA, and trademark-based interventions must be limited to ensure there is no harm to the public interest.**

At the outset, the Agreement was intended to address only copyrights and some forms of trademark infringement. Yet recent disclosures of the text indicate that the scope of the Agreement has now extended far beyond what is necessary, with respect to enforcement of intellectual property rights, supposedly to discourage or arrest the trade in counterfeit goods.

Counterfeit goods, under the WTO TRIPS Agreement, are 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;

Although the TRIPS Agreement does not forbid inclusion of patents under a definition of counterfeiting, TRIPS negotiators specifically excluded patents because patents have no bearing upon whether a product is counterfeit. Ascertaining patent infringement involves a complex legal and scientific dispute between two private parties concerning the scope, validity and use of an invention, and does not involve a wilful effort by one private party to misrepresent or mislabel a product.

Incorporating patents in ACTA will do nothing to arrest the proliferation of counterfeit products, including counterfeit medicines. Instead, introducing new standards to increase enforcement of patents will merely discourage legitimate challenges to patents. In many cases, legitimate challenges to patents, especially against patents filed by multinational pharmaceutical companies, can

discourage frivolous patenting practices that result in "ever-greening", or the extension of patent terms far beyond the twenty years of protection granted under TRIPS.

In intellectual property usage, the term counterfeit, as regards medicine, correctly applies only to wilful trademark infringement. With respect to pharmaceuticals, only a subset of trademark infringing medicines (or other goods) poses a risk to public health. These include deliberately mislabelled medicines which fraudulently misrepresent their source or ingredients to consumers. In fact, medicines that are substandard (and even some contaminated or adulterated medicines) and pose a risk to public health can be both branded and generic, but may not infringe on trademarks or otherwise violate intellectual property rules.

In some situations, generic medicines may have an unintentional semblance to a branded medicine, particularly since both branded and generic medicine can legitimately rely on the international non-proprietary name (INN) to mark its own product. Generally, generic medicines (or other goods) unintentionally bearing symbols or words that could be confused with trademarks cannot be said to pose a categorical risk to public health.

For these aforementioned reasons, trademark analysis and trademark enforcement runs the danger of being both over and under inclusive, targeting legitimate generic medicines or failing to identify substandard, and even some adulterated or contaminated medicines. Negotiators must ensure that trademark measures are narrowly circumscribed to wilful and intentional trademark infringements where there is a clear effort to intentionally mislabel a medicine. This should be accompanied by rigid anti-abuse provisions to ensure trademark enforcement measures are not abused by rights holders.

3. Border measures and new criminal enforcement penalties present a particular threat to access to medicines and must be circumscribed.

Negotiating parties are implementing border measures and criminal enforcement penalties to restrict the trade in counterfeit goods. If the scope of the Agreement ultimately includes goods suspected of patent infringement and all forms of trademark infringement, it is critical that parties to the negotiation exclude border measures or criminal penalties for goods-in-transit involving patent or civil trademark determinations of infringement. This should include both *ex officio* border measures by border officials and seizures at the border based upon requests by patent holders. Negotiating countries should also have the option to not include border measures or criminal enforcement measures, within their own territory, for goods suspected of patent or unintentional trademark infringement.

Border measures, especially for goods-in-transit, pose a serious threat to access to medicines. Border measures for goods-in-transit have resulted in the seizure within the European Union (EU) of shipments of legitimate and safe generic medicines, en route from either India or China to developing countries.

implementing the aims, objectives and rules of the Agreement. The new committee would:

- Supervise the implementation of ACTA
- Consider further "elaboration" or "development" of the agreement
- Address "disputes that may arise regarding the interpretation or application" of ACTA
- Consider any other matter that may affect the operation of this agreement.

Oxfam is concerned that such a Committee would usurp authority on intellectual property matters that normally belong at either the WTO, WIPO or at the national level, and that the Committee would further expand its ambit to include other issues, such as substantive intellectual property rules, which would subsequently be established as the new global standard for intellectual property protection worldwide.

Oxfam hopes that negotiating parties, who have decided to formulate this agreement in secrecy, outside of established multilateral forums, and without any scrutiny as to its consequences upon developing countries, will resist the temptation to declare the ACTA Oversight Committee as the new locus of decision-making on intellectual property matters and instead will leave authority at the two major multilateral institutions as well as to countries.

Non-governmental organisations, especially those that provide critical input to protect the public interest, must be given full access and opportunity to observe and to ultimately participate in discussions at any such Oversight Committee.

Finally, the New Zealand Government must refrain from including ACTA provisions, which are likely to be inappropriate for developing countries, in future trade negotiations, such as the extension of the Pacific Agreement on Closer Economic Relations with the Forum Island Countries.

Conclusion

Oxfam New Zealand appreciates the opportunity to provide these written comments in advance of the next round of the Anti-Counterfeiting Trade Agreement. For the reasons outlined above we believe ACTA could have serious consequences for the ability of people living in developing countries to gain access to life-saving medicines. We welcome the opportunity to discuss our submission in advance of the upcoming negotiation.

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Specifically, 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 multinational 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.

Criminal penalties for products labelled as counterfeit due to suspected patent infringement or unintentional trademark infringement create additional barriers to access to medicines. Manufacturers of generic medicines may hesitate or forego production of medicines that will be seized out of concern of criminal or financial liability. This invites multinational pharmaceutical manufacturers to use rules intended to curb the unlawful trade in counterfeit products to impose new barriers that are likely to result in excessive and anti-competitive monopolies for pharmaceutical products.

Thus, measures to enforce patents under ACTA will result in delays or barriers to exporting medicines to developing countries, and will catalyse an upward harmonization of patentability standards. This will increase medicine prices in developing countries and, as a result, could ultimately lead more poor people to purchase counterfeit and fake products due to unaffordable prices of legitimate products, ultimately costing lives.

Similarly, overly-broad trademark enforcement runs a serious risk of preventing or delaying the lawful trade in legitimate generic medicines that may unintentionally infringe the trademark of a branded pharmaceutical company.

4. **Any powers granted to a new 'ACTA Secretariat' must be limited in nature, and should not exceed or replace any authority already granted to the WTO and WIPO, and developing countries should not be required to sign up to ACTA provisions as part of trade negotiations. All non-governmental organisations should be given full opportunity to engage with the ACTA Secretariat and to observe and participate in subsequent discussions.**

Recently disclosed texts indicate that negotiating parties to ACTA intend to establish a new 'Oversight Committee' that would be responsible for