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Oxfam Submission regarding the Anti-Counterfeiting Trade Agreement (ACTA)

Oxfam Canada and Oxfam-Québec are concerned that the Anti-Counterfeiting Trade Agreement (ACTA) under negotiation will undermine access to affordable medicines, which is a key element of Canada's efforts to strengthen the health systems of developing countries and stem the spread of disease.

While our knowledge of the contents being negotiated is limited by the secrecy of the parties, we understand that enforcement of patent protection via border measures and criminal penalties is on the table. Identifying and seizing fake medical products is a valid and urgent multilateral enterprise, since substandard medicines are a serious public health risk. But assessing patent infringement is irrelevant to the task of fighting the criminal networks that purvey substandard medicines. Furthermore, such an approach may undermine the supply of legitimate affordable medicines to developing countries.

The focus of public efforts should be on removing substandard medicines, counterfeit or not, from the supply chain and on improving the quality of legitimate pharmaceutical products. This is a drug regulatory and safety import issue, requiring improved national drug regulatory bodies and investment in quality control procedures in plants through the supply chain. It has nothing to do with intellectual property rights.

We reject the notion that medicines that infringe (or may infringe) patents should be considered counterfeit. Counterfeit medicines have safety risks; those subject to patent disputes, produced openly in regulated facilities, do not. A counterfeit medicine, under the traditional World Health Organization definition, is one that is "deliberately mislabeled." To broaden the definition to include medicines that may infringe on intellectual property rights not only fails to address the very real public health threat of substandard or spurious medicines, it would draw public resources away from that urgent task.

Counterfeiting historically applies to only trademarks, without any real relevance to patents, data protection or trade secrets. We urge Canada maintain the standard practice under the TRIPS Agreement of each country enforcing IP rules at the national level and scrupulously avoiding multilateral enforcement of intellectual property rights.

Under proposed ACTA measures, multilateral enforcement could legitimize and generalize the practice of seizing legitimate shipments of generic medicines in transit merely on the suspicion of violating a patent, as occurred 18 times in recent months in the European Union.

Such seizures contravene the spirit of the TRIPS Agreement and the Doha Declaration on TRIPS and Public Health, and could jeopardize the use of Canada's Access to Medicines Regime (CAMR). If a medicine is exported legally under CAMR to a developing country via a country that introduces such border measures, the medicine could be seized if under patent in the transit country.

More broadly, the proposed ACTA measures shift a private responsibility onto the public's shoulders. Normally rights holders must seek financial compensation and injunctions in court ('private vigilance') for patent infringement. Measures proposed for ACTA, however, would place the burden on taxpayers by requiring customs officials to enforce IP rights. This diverts scarce resources from the public sector while failing to address the real problem of substandard medicines.

We understand one proposal would expand criminal penalties for what are traditionally civil trademark violations – 'trademark infringement caused by confusingly similar trademark goods.' The TRIPS Agreement states that trademark infringement must be deliberate or fraudulent, but proposals would include cases when there is no intent to deceive or any likelihood of confusion with the authorized manufacturer.

For example, under EU rules amoxicillin was seized in Germany because the name used by a generic manufacturer was similar to the international non-proprietary name. Targeting medicines that are not labeled clearly as to its origin (pedigree) or are similar to others, as if they were counterfeit, could seriously curtail parallel imports, since medicines that enter a market through parallel imports are often repackaged. And parallel imports are a crucial source of medicines for poor countries.

We understand another proposal would change the rules with respect to infringement to limit the issuance of compulsory licenses when infringement occurs (which is allowed under the TRIPS Agreement) and replace it with court injunctions. The current practice under TRIPS (Article III) is to allow for patent infringement to occur and to issue a license that allows the generic producer to use the patent for a license fee.

We do not agree with an aggressive definition of infringement that exceeds the standard under the TRIPS Agreement. Counterfeiting clearly means deliberate or fraudulent infringement and must not be expanded to include infringement when there is no intent to deceive or any likelihood of confusion with the authorized manufacturer. Legitimate, safe and effective generic medicines are not counterfeit.

Finally, we fear that heightened enforcement of patent monopolies will actually lead to an increased presence of counterfeit medicines in the supply chain. High prices are what drive the supply of counterfeits, and measures which threaten the legitimate trade in generic medicines will only drive prices higher.

Recommendations

The ACTA negotiations offer an opportunity for Canada to show leadership on the world stage, protecting and enhancing the fragile flexibilities in patent rules that allow poor people access to affordable medicines. We urge Canada to firmly oppose all attempts to introduce multilateral enforcement of patent rules.

Specifically:

1. Maintain the WHO definition of counterfeits as the willful or fraudulent infringement of trademarks. Canada should insist that mere infringement of trademark/copyright should not be included in the agreement and that there be no inclusion of patent infringement.
2. Do not undermine technology transfer. Canada should promote expanded flexibilities for sharing of technology, and therefore oppose increasing the use of injunctions that will impede compulsory licensing.
3. Allow legitimate trade. Canada should oppose any measures that interfere with parallel imports or goods in transit, which is of particular concern for Canada's Access to Medicines Regime.
4. Public resources should be dedicated to public concerns. Canada should keep patent infringement from being subject to criminal penalties, and oppose rules that require customs officials to take responsibility for IP enforcement at the expense of other pressing health and safety needs.
5. Transparency is crucial. Canada should insist that no further negotiations occur until the texts are made public. Developing countries, in particular, must be allowed to see the texts and provide input.

Submitted by

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