

## **Berkeley Declaration on Intellectual Property Enforcement and Access to Medicines**

All people have the right to access the medicines they need to be healthy. As public health groups, humanitarian and inter-governmental organizations, experts and academics that work on access to medicines, we gathered at the University of California at Berkeley to analyze the serious threats that recent “intellectual property enforcement” initiatives pose to this right. The enforcement agenda threatens the last decade of efforts to achieve access to medicines for people in low- and middle-income countries, and compromises the attainment of health-related Millennium Development Goals. We make this Declaration to call upon policy makers in governments and international organizations to reject the cynical and dangerous efforts that have been made through this agenda to prioritize commercial interests over the right to health.

The IP enforcement agenda promotes new standards that will require increased surveillance of goods and more intrusive police powers for government officials without adequate procedural protections. It aims to substantially increase the penalties for people alleged to have infringed patents, trademarks, and copyrights. It would require judges to consider a range of measures that would restrict the freedom of people to use knowledge goods, and would impose new punishments for third parties without due regard for the implications on access to medicines.

Access to medicines in developing countries depends on the ability of countries to produce, export, and import generic medicines. Restrictions on generics impede competition, leading to increased prices, and preventing people with limited resources from accessing the medicines that they need. New enforcement measures have been used by customs officials to disrupt the supply of legal generic medicines between developing countries as they transit through Europe. The draft Anti-Counterfeiting Trade Agreement (ACTA) represents a deliberate and non-transparent attempt to bypass multilateral institutions, while ultimately aiming to impose its standards on developing countries. The enforcement agenda commandeers public money for private gain, and has a chilling effect on the manufacturing of and trade in legitimate generic medicines. Contrary to assurances, it undermines key public health safeguards that allow countries to balance the right to health with their obligations under the World Trade Organization’s Trade Related-Aspects of Intellectual Property Rights Agreement (TRIPS). While enforcement norms are typically considered procedural, it is clear that this new agenda goes far beyond procedures and has serious implications for substantive areas of intellectual property law.

The recent IP enforcement agenda is being promoted in many fora: globally, in the ACTA negotiations; regionally, with the East African Community draft “anti-counterfeit” policy and Bill; and nationally in free trade agreement negotiations with the European Union and national “anti-counterfeiting” laws, among others.

Additional sites of these initiatives include the World Customs Organization SECURE project, the World Health Organization International Medical Products Anti-Counterfeiting Taskforce (IMPACT), and Interpol. Public safety is being cynically used as a pretext to promote these initiatives. In particular, we reject the attempt to conflate the serious public health issue of medicines quality with private concerns about the enforcement of intellectual property rights.

IP enforcement initiatives must not interfere with access to medicines, and should:

- Be grounded in human rights principles
- Protect innovation, competition, and consumer rights
- Be negotiated through a transparent, inclusive, and open process, that does not bypass existing multilateral institutions
- Protect the full use of TRIPS flexibilities that promote access to medicines

ACTA represents some of the worst enforcement practices on both substance and process. The agreement has been conducted through a secretive, illegitimate process, and there is no evidence that its procedural or substantive shortcomings can be remedied in the current structure. ACTA should be abandoned.

The European Union should cease its efforts to export its much-criticized enforcement policies to low- and middle-income countries. We call for a moratorium on exporting these policies through free trade agreements and technical and financial assistance. The review of EU customs regulations that was prompted by the recent generic drug seizures must be concluded with amendments to these regulations that remedy the threat that they pose to access to medicines.

The East African Community “anti-counterfeiting” draft policy and proposed legislation introduces unprecedented IP norms at the regional level, threatens access to medicines, and should be discarded. It is particularly inappropriate because it seeks to impose TRIPS-plus provisions when TRIPS itself does not require the majority of the participating countries to enforce patents on medicines. The East African Legislative Assembly, national governments affected, and the EU Parliament should investigate the origins of such laws at the national and regional level. We also welcome efforts made to challenge the recent “anti-counterfeiting” law in Kenya in court.

We recommend all developing countries approach IP enforcement and “anti-counterfeiting” initiatives with caution and reject any such initiatives that affect the ability to produce, export, import, and use generic medicines. We also call for enhanced South – South collaboration in developing frameworks for the management of IP from a public health perspective.

Finally, WHO should immediately disengage from IMPACT, and instead take a public health approach to the problem of medicines quality, safety, and efficacy. Such an approach must strengthen drug regulatory authorities, ensure the availability and affordability of medicines to diminish incentives for unregulated and unsafe

medicines, promote rational use, and require transparency and accountability in the pharmaceutical sector. WHO should scrutinize and publicize the implications of IP and its enforcement on public health, and WHO member states should focus on and lead the implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

Against the background of continued problems with excessive drug prices, falling donor commitments, the real danger of not meeting Millennium Development Goals targets, and the failure of the TRIPS Agreement to meet the expectations of developing countries on access to medicines, innovation for unmet health needs, and technology transfer, a focus on IP enforcement is hypocritical and immoral. It will deepen global health inequality, and exacerbate inequity in access to medicines.

*Signed*

Farmamundi

Health Action International Africa

Knowledge Ecology International

Public Citizen

Third World Network

Universities Allied for Essential Medicines

William L. Aldis MD, Assistant Professor (Global Health), Faculty of Public Health, Thammasat University, Bangkok, Thailand

Kajal Bhardwaj, Lawyer (HIV, health and human rights), India

Michelle Childs, Director Policy Advocacy, Médecins Sans Frontières Campaign for Access to Essential Medicines

Gwen Hinze, International Director, Electronic Frontier Foundation

Busingye Kabumba, Lecturer on Law, Human Rights and Peace Centre (HURIPEC), Makerere University

Amy Kapczynski, Assistant Professor of Law, University of California at Berkeley Law School

Els Torreele, Project Director, Access to Essential Medicines Initiative, Open Society Institute

German Velasquez, Senior Adviser for Health and Development, The South Centre, Geneva

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