



The Drug Monopoly Enforcement Agenda

Overreaching IP Enforcement and Risks to Generic Medicines & Competition

High prices create an access to medicines problem. Generic medicines allow for market competition, thus reducing prices.

Recent trends in IP enforcement will chill trade.

- New measures protect patent and copyright monopolies under the guise of fighting counterfeits and piracy.
- New measures create uncertainty for generics firms.
- New measures restrict availability and free movement of licensed medicines.
- New measures impose high costs by conflating distinct IP rights and applying “counterfeit” too broadly
- New measures are more likely to snare non-infringing competitors.

Recent trends in IP enforcement will harm consumers.

- New measures place the focus on counterfeiting, an under-inclusive proxy for protecting against substandard drugs.
- New measures place the enforcement burden of private IP rights on the public.
- New measures will create opportunity costs by not protecting consumer health & safety more directly.
- New measures thwart price-lowering competition.

The “Dutch Seizures” are an example of recent enforcement measures jeopardizing health.

- Dutch customs officials seized licensed generic medication based on patent infringement claims, even though drugs were not infringing patents in countries of origin or destination.
- ACTA and other proposed legislation would allow such seizures to continue and would drastically hurt competition.

U.S. legislation reflects the broad IP enforcement agenda.

- The *Stop Counterfeiting in Manufactured Goods Act, 2004 Amendments* increases counterfeiting penalties and enforcement powers.
- The *Pro-IP Act* creates an IP czar position.
- The *IP Enforcement Act* increases fines and forfeiture of property for both civil and criminal infringers.

National legislation in East African countries reflects these harmful trends.

- Legislation includes: Kenya’s Anti-Counterfeit Act, Tanzania’s regulations, Uganda’s proposed laws.
- New legislation makes the importation and sale of “counterfeit goods” a criminal, instead of a civil, offense.
- New legislation gives powers to customs officials and police to differentiate generics from fakes.
- New legislation will severely hurt AIDS/HIV treatment programs by reducing access to antiretroviral drugs.

ACTA exemplifies the problems of overreaching IP enforcement.

- ACTA conflates social interests in preventing counterfeit medicines and private IP rights.
- ACTA blocks competition more than it protects public safety.
- ACTA’s provisional measures include over-broad customs authority and harsher penalties for infringers.