



## **Protecting Health & Competition under IP Enforcement**

### *Protecting Against Unintended Anti-consumer & Anti-competitive Effects of IP Enforcement*

IP enforcement measures are an indirect method of protecting against falsified and fraudulently mislabeled medicines. While there are more direct methods for ensuring consumer safety, the following suggestions for proposed IP enforcement agendas will at least aid in preventing the costs of IP enforcement from exceeding the benefits.

#### ***Prevent Harm to Existing Competition & Safety Measures***

- Ensure enforcement measures do not harm generic medicine supply chains.
- Take into account all of the interagency and international efforts and tools already in use to protect health, safety and consumers.
- Assess opportunity costs that could arise from protecting health and safety through IP enforcement rather than more direct mechanisms.

#### ***Ensure Scope of Private IP Rights is not too Broad***

- Patent status, an improper proxy for drug quality, should not be used to detain medicines at borders.
- Measures must distinguish between criminal and civil patent/trademark infringement.
- Measures must treat trademarks, patents and copyright as distinct rights, with distinct remedies.
- Detention/seizure of medicines only for willful trademark counterfeiting on a commercial scale.
- New measures cannot eliminate TRIPS flexibilities, such as compulsory licensing.

#### ***Protect Generics Competitors from the Push to Catch Infringer***

- Consider interests of licensed businesses attempting to compete in the global market.
- Include anti-abuse provisions to deter wrongful action by private parties or public authorities.
- Provide procedural safeguards to protect medicines manufacturers from costly rights enforcement errors.
- Require evidentiary standards to protect medicines manufacturers from costly rights enforcement errors.
- Restrict third party liability, specifically active ingredients manufacturers.
- Prevent pharmaceutical patent holders from enforcing patents that they have not disclosed publicly.

#### ***Provide Transparency***

- Release drafts of texts.
- Allow stakeholder participation.
- Allow public input, specifically in the deliberation of shifting to public enforcement of private rights.