



Protecting Consumers from Unsafe & Fraudulent Products *IP Enforcement Measures Offer Indirect & Incomplete Consumer Protection*

Overview

- New IP enforcement measures are an indirect & incomplete framework for protecting health & safety.
- Protecting public health and safety is being used as a justification for these new measures.
- If IP measures are too broad, the costs of harming generics competition will outweigh the benefits of catching a small portion falsified medicines.

Patent infringement presents a poor framework for protecting health & safety.

- Patent infringement is not reasonably related to public health and safety.
- A proven patent infringement is no basis whatsoever for classifying a medicine as counterfeit.
- The alleged infringer is usually attempting to manufacture or market a legitimate medicine.
- Imprecise or overly aggressive patent enforcement measures could obstruct generics competition.

Copyright Infringement is not reasonably related to protecting health & safety.

IP enforcement measures should only cover willful trademark counterfeiting on a commercial scale.

- Measures must distinguish between trademark counterfeit and civil infringement.
- Counterfeit must only apply to a mark that is identical to or indistinguishable from a registered trademark.

Civil trademark infringement claims should not be a basis for border seizures.

- Civil infringement occurs in the course of legitimate trade.
- Civil infringement is not criminal in nature; there should be no intervention ahead of the judicial process.
- The court's multi-factor "likelihood of confusion" test is beyond the skill sets of customs officials.
- Generics are prone to invalid claims due to necessary similarities in appearance to brand name drugs.
- Allowing civil infringement measures may lead to spurious rights holder claims.

Trademark infringement is over- and under-inclusive in promoting health & safety.

- Fraudulent misrepresentation may exist where no trademark is copied.
- A product infringes a trademark because it is a fake but may be fake without infringing a mark.
- Regulatory agencies can protect against substandard medicines better than a trademark analysis can.

Public health costs of using a trademark framework include:

- Detention/seizure of shipments, when litigation/traditional remedies can protect mark holder's interests.
- Over-enforcement of IP rights with the push to catch infringers and no incentives to protect competition.
- Creation of monopolies, which eliminates competition and prohibits lower prices.
- Under-investment in more direct and efficient remedies.

More direct options for protecting health & safety:

- *Fraudulent misrepresentation of source & fake packaging*, as is currently used in routine customs inspections. Trademark analysis adds nothing in determining drug quality.
- *Drug regulatory rules & law enforcement powers to protect against public endangerment* have broader authority to protect consumers against substandard medicines.
- *Statutory disclosure requirements* mandating that companies disclose information of potentially dangerous fakes to authorities in a timely fashion.
- *Private vigilance of marks* as a complement to public vigilance and safety efforts.

Because there is an indirect relationship between IP infringement and substandard medicines, public health and safety is not adequately protected through IP enforcement.