



Protecting Health & Competition under IP Enforcement *Customs Should Stop Criminal Activity, Not Generic Competition*

Customs enforcement of IP rights must be restricted in order to prevent harm to generics competition. Legitimate, non-counterfeit generics were seized in the EU for alleged trademark infringement. These medicines were in transit and did not infringe any IP rights in the countries of origin or destination.

Costs of Overreaching Customs Measures

- Restricts availability and free movement of legitimate generics.
- Chills trade due to uncertainty and imposition of excessively high costs.

Criminal Counterfeiting vs. Civil Infringement

- Criminal counterfeiting requires three elements:
 - Intent to deceive.
 - A mark that is identical or indistinguishable from the protected mark.
 - Production on a commercial scale.
- Civil Infringement does not involve require willful intent and involves a “likelihood of confusion” test.

Border measures must distinguish between criminal counterfeiting & civil infringement.

- Civil infringement plays no role in protecting public health and safety.
 - With no risks to health and safety, medicines should not be detained.
 - Rights holders can recover through litigation/damages instead of delaying legitimate medicines.
- Licensed generics are prone to civil infringement claims.
 - Generics often have similar names to the brand name drug due to similar active ingredients.
 - Generics often have similar pill color and packaging to prevent confusion amongst pharmacists and patients.
- Civil infringement involves a multi-factor “likelihood of confusion” test, which is better left to judicial expertise.

Seizures must be restricted to willful, commercial scale trademark counterfeiting & copyright piracy.

- Patent and civil trademark litigation is too complex for analysis by customs officials.
- Many customs detentions are never fully subsequently litigated, thus preventing delivery of medicines.
- Giving customs officials the power to seize medicines may lead to spurious rights holder claims.
- Officials are likely to err on the side of over-enforcement when told to stop any suspected IP infringement.

Restrictions to IP regulation for in transit goods are a necessity.

- States have no grounds for impeding free movement of legitimate goods from one country to another.
- Medicines may not infringe patents or trademarks in countries of origin and destination.
- Stopping legitimate, in transit goods creates a de facto international IP regime.

Granting too much authority to customs agencies creates global costs to competition.