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The Drug Monopoly Enforcement Agenda

ACTA: An Example of the Dangers of Overreaching IP Enforcement

The U.S., E.U., and key trading partners are negotiating an Anti-Counterfeiting Trade Agreement (ACTA). ACTA is one of several major new initiatives seeking, in part, to protect drug monopolies under the guise of fighting counterfeits.

ACTA will keep medicine prices high.

- ACTA's Elements Under Discussion could restrict availability and free movement of generic medicines.
- ACTA will worsen the rampant problem of seizures of legitimate medicines at national borders.
- ACTA is likely to reduce generic competition, resulting in higher prices for consumers.

ACTA will chill trade due to uncertainty & financial costs for manufacturers.

- ACTA will allow seizures of in transit generics that do not infringe patents in country of origin or destination.
- ACTA imposes robust penalties, litigation, and storage fees on alleged infringers, without adequate safeguards or anti-abuse provisions.
- ACTA imposes harsh damage awards and injunctive relief on civil infringers.
- ACTA proposes liability for third parties, such active pharmaceutical ingredients manufacturers.
- ACTA is not limited to counterfeit medicines and allows seizures for civil trademark infringement claims.
- ACTA does not consider the interests of accused infringers.

ACTA fails to adequately address public health & safety concerns.

- Patents are not reasonably related to counterfeiting or drug quality concerns.
- Copyright is not reasonably related to health or safety.
- Trademark is unnecessary to protect the drug supply; a better policy would specifically target fraudulent and deliberately mislabeled drugs.
- Serious health and safety measures are absent from ACTA proposals.
- ACTA's costs to competition and access to medicines outweigh its claimed safety benefits.

ACTA enforces private monopolies at public cost.

- ACTA shifts the burden and cost of enforcing private rights to taxpayers.
- ACTA diverts law enforcement and border protection resources from other public priorities.
- ACTA's broad new standards for damages & injunctive relief could hinder innovation & economic growth.
- ACTA changes the nature of private rights without needed legislative debate and analysis.

Public Citizen urges, at a minimum:

- Increased transparency and stakeholder participation in negotiations.
- Elimination of patent status as a medicine detention trigger.
- Rejection of non-counterfeit trademark similarity as a medicine detention trigger.
- Strong procedural safeguards and evidentiary standards for border measures.
- Robust anti-abuse & liability provisions adequate to deter wrongful seizures at borders.
- Consideration of the legitimate interests of licensed businesses attempting to compete in a global market.
- Assurance that enforcement measures will not compromise generic medicine supply chains.