Counterfeit confusion:

Is Intellectual Property enforcement the solution for dealing with fake or substandard drugs?

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Laws Governing Pharmaceuticals

- **Drug laws and regulations**
  - assure the **Q**uality, **S**afety, and **E**fficacy of pharmaceuticals
  - directly health-oriented

- **Trade-related laws and regulations**
  - IPR laws
  - provide protection of property rights of private entities
  - irrelevant to health of consumers

Counterfeiting confusion in health and IPR areas

Counterfeit drugs

- **Drugs which are deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products. Counterfeit products may include products with correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging.**

WHO definition

Counterfeit drugs [2]

- Counterfeit drugs
  - focus made on **poor-quality** and **unsafe** medicines that can potentially cause harms to patients' health
  - not relate to private entities' property rights like IPR, focusing on protection of benefits entitled

Counterfeiting in IPR area

- **Counterfeit trademark goods** shall mean any goods, including packaging, *bearing without authorization a trademark* which is identical to the trademark validly registered in respect of such a goods, or which cannot be distinguished in this essential aspect from such a trademark , and which thereby ***infringe*** *the rights of the owner of the trademark* in question under the law of the country of importation

TRIPS Part III, Section 4, Art 51

Counterfeiting in IPR area [2]

- **Counterfeit trademark goods**
  - not use the term “counterfeit goods”
  - what is counterfeiting is trademark
  - quality of the goods not mentioned
    - may be same, lower, or even better
    - just bearing unauthorized trademark
  - aim at protecting the rights of a trademark owner for trade advantages

TRIPS Part III, Section 4, Art 51

Why confusing?

How about **good** medicines bearing an accused counterfeit trademark??

Two separate issues

- **Good** medicines
  - medicines with assured quality, safety and efficacy by responsible drug authorities, and receiving marketing authorization

- **Accused** counterfeit trademark
  - Civil dispute over the rights of a trademark owner
  - not relate to any health concern

How about counterfeit medicines bearing a counterfeit trademark?

Draft EU-ASEAN FTA (IPR)

- For the purpose of this provision (i.e., Border Measure), "**goods infringing IPRs**" means

  [1] Counterfeit goods; i.e.,

  - Counterfeit trademark,
  - Counterfeit trade symbol (logo, label, sticker, brochure instruction for use or guarantee document)

  [2] Pirated goods;

  [3] Goods, which according to the law of the Party in which the application for the custom action is made, *infringe*:

  - **a patent**;
  - a plant variety right;
  - a design;
  - a geographical indication

Solution for Counterfeit Medical Products

- **Aim** "…protect public health and promote access to more affordable, safe, efficacious, and quality medical products (including medicines)."

- **Mechanism:** "…building up and strengthening the technical and scientific capacities of **national drugs authorities** with adequate regulatory infrastructure to achieve their mission of assuring the public the quality, safety, and efficacy of medical products, while **excluding trade and IPR considerations."**

Tackling Counterfeit Medical Products Problems

stick to public health context

Do not count on IPR enforcement framework!

Thank you for your attention