

# **Two topics: Non-Voluntary uses of medical patents, and delinkage of R&D costs from drug prices**

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31 May 2013  
Athens

# What are non-voluntary authorizations to use patents?

Several names used to describe non-voluntary authorizations, including non-remunerative and remunerative exceptions.

Typical names for exceptions involving remuneration include:

- Compulsory licenses
- Government use of patented inventions
- Licence to the Public Sector
- Limitations on injunctions and other remedies for infringement
- Remedies to anticompetitive practices (some even have zero remuneration)
- Ex-officio licenses
- Etc

The term "compulsory license" often used a generic term for non-voluntary authorizations that involve remuneration or remedy anticompetitive practices

# Motivation for compulsory licensing of patents

Patents are used to create a legal monopoly on an invention, and this can lead to high prices, barriers for access, and also limit innovation as regards new products.

Compulsory licenses, authorized by governments or courts, can break the monopoly and permit one or more competitors to drive prices down, or use the invention in a new product

# Compulsory licensing in some other countries

- **USA.** Recent compulsory licenses involve patents on medical devices, software, automatic transmissions, and many other technologies. Threat of CL used by NIH in 2004 to reduce public sector prices of an AIDS drug by 80 percent.
- **Germany.** CL often part of infringement disputes. Roche used German CL law to obtain license to patents on HIV/AIDS diagnostic test.
- **Italy.**
  - 2005, compulsory license for Merck patents on antibiotics that use Imipenem Cilastatina.
  - 2006, compulsory licence to Fabbrica Italiana Sintetici SpA (FIS) for manufacture of Sumatriptan Succinate, for migraine medicines.
  - 2007, royalty free licences to allow manufacture and sale of active ingredient finasteride to treat cancer of the prostate, and male-pattern baldness.
- **France.** Proposed with RU 486 withdrawn from market. With Belgium, expanded ex officio licensing authority for patents on genetic tests.

On March 18, 2013, Essential Inventions sent a letter to Greece Ministry of Health Andreas Lykourantzou, requesting both a cooperative agreement and a non-voluntary authorization to use patents on pharmaceutical drugs for cancer, HIV/AIDS and other diseases and conditions under Article 14 of the Greece patent law.

Governments will not provide universal access to new medicines unless they deal with patents and other intellectual property issues

If the Greece government rejects to the proposal for compulsory licenses, patients who have cancer will continue to have limited access to medicines, and this will result in people dying unnecessarily for lack of access to treatments, and also financial hardships on those who manage to buy the medicines.

# De-Linkage model

The WHO has proposals for new approaches to funding R&D, that delink R&D incentives from drug prices.

One proposal is for a Cancer prize fund. Countries create an innovation inducement prize fund to reward successful innovation for new cancer drugs, but demonopolize cancer drugs.