

# Compulsory Licensing and Government Use of Patents for Pharmaceuticals

**Compulsory licensing** (including government / crown use, as well as court-issued remedies to anti-competitive practices) is a standard and long-standing flexibility in patent rules. The introduction of **generic competition has consistently proven the most effective way to reduce the price of medicines**, and ensure prices continue to fall with time. Medicines under compulsory license (CL) may be manufactured for domestic use, imported, or, with certain conditions met, exported. Public programs, the private sector, or both, may manufacture and distribute the licensed generic products to patients, depending on the terms of the compulsory license.

## Compulsory Licensing

**Compulsory licensing allows governments to authorize generic competition** with patented medicines in exchange for royalty payments to patent holders. It is a flexibility included in the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO's TRIPS, Article 31, "Other Use Without Authorization of the Right Holder").

According to Article 1.1 in TRIPS, "**Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.**"

The **Doha Declaration of 2001** clarifies countries' health rights under TRIPS and affirms that **TRIPS should be interpreted in a manner supportive of a country's right to protect public health and promote access to medicines for all.**

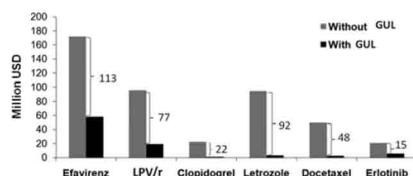
## HIV/AIDS

- **Malaysia** issued "government use" licenses for the import of three patented AIDS medicines in 2003. The average cost of treatment dropped by 81%, from \$315 to \$58 per patient per month. The CL enabled the number of HIV/AIDS patients treated in public hospitals to increase from 1,500 to 4,000.
- In 2005, **Brazil** proposed to use a CL for lopinavir+ritonavir (Kaletra) on public interest grounds. Abbott, the patent holder, immediately reduced its price by 46%. In 2007, **Brazil** used a CL for efavirenz which produced immediate savings of US\$31.5 million.
- **Thailand** used a CL for efavirenz (EFV) and lopinavir+ritonavir (lpv/r) in 2006 & 2007. By 2010, the number of patients receiving EFV increased from 4,539 to 29,360 and the number of patients using lpv/r more than tripled. After the CL, Abbott cut the price of lpv/r by more than 55% for over 40 countries.
- **Indonesia, Mozambique, Zambia, Eritrea, Ghana, & Ecuador** have also used a CL for HIV/AIDS medicines.

## Non-Communicable Diseases

- In 2008, **Thailand** issued licenses for several cancer medicines. Competition enabled the price of docetaxel and letrozol to drop 24 and 70 times respectively. In 2007, Thailand's CL for clopidogrel, a cardiovascular treatment, induced an estimated 91% price reduction.
- In March 2013, the Intellectual Property Appellate Board of **India** upheld a CL issued by the India Patent Controller for local manufacturer of sorafenib. The price of the medicines is expected to drop by 97%, from US\$5,500 to US\$175 per patient per month.

Comparison of public expenditure in Thailand with and without the government use license (GUL) by treatment (in million US dollars)



Source: A. Mahoro, et al., "Impact of the Introduction of Government Use Licenses on the Drug Expenditure on Seven Medicines in Thailand," *Value in Health*, vol. 15, 595-599, 2012.

In 2007, **Italy** ordered Merck to grant free licenses to local generics for a treatment against prostate cancer and male baldness to correct anti-competitive practices. The licenses were royalty-free.

The **United States** uses compulsory licensing across a variety of technological sectors, including via judicial remedies to anti-competitive practices. The U.S. government has the right to use any patent for any invention, for any government purpose. No special authorization is required nor is there a need for prior negotiations. (28 USC 1498(a))

