Regional Seminar for Certain African Countries on the Implementation and Use of Several Patent-Related Flexibilities

Topic 10: The Use of Compulsory Licenses

Durban, South Africa
January 29 to 31, 2013
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TOPIC 10

- The use of compulsory licenses
- The experience of Zimbabwe

Presenters
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According to Section 35(1) of Zimbabwean Patents Act:

35. (1) During any period of emergency the powers exercisable in relation to an invention by a department of the State or a person authorized by the Minister under section thirty-four shall include the power to make, use, exercise and vend the invention for any purpose which appears to the Minister necessary or expedient—

for the maintenance of supplies and services essential to the life of the community; or for securing a sufficiency of supplies and services essential to the well-being of the community [...]
In 2002 the Minister of Justice, Legal and Parliamentary Affairs declared a period of emergency due to HIV/AIDS pandemic valid for 6 months. The intention was to utilize this option to improve access to ARVs.

In 2003 the period of emergency was extended by 5 years (- 31 December 2008) and compulsory license was issued to either import or make ARVs.

This was further renewed by 10 years through SI 49 of 2009: now expiring in 2019.
Zimbabwe compulsory licensing

- In a letter of authorization by the Minister of Justice, Varichem Pharmaceuticals was commissioned to produce ARVs or HIV/AIDS related drugs.
- They were to supply three quarters of their product to state owned health institutions.
- The ARV roll out program is funded mainly through government budgetary allocations with some assistance from NGOs. In 2003 Varichem’s first generic ARV Varivar was launched.
- Accordingly, the price of AZT/3TC comes down from US$30 per month to less than US$15 a month.
Challenges

- The blanket approach
  - This discourages patent holders from registering their patents in Zimbabwe
- High duty and VAT charged on raw materials used to manufacture ARV tend to increase the cost of production and of the end product
- Lack of market access
  - High cost of drugs
  - Donors prefer to import
Conclusion

- Compulsory licenses are a powerful tool for reducing prices / increasing access to medicines
- Compulsory licenses are an effective tool for limiting the impact of certain patents and bringing discipline to the IP industry
- For compulsory licenses to be really effective, developing countries need develop policies that recognize the importance of innovation and develop capacity for local innovation and production
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