USE OF PATENT RELATED FLEXIBILITIES AND THE MAIN CONSTRAINTS THEREON WITHIN THE REGION

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Outline

- Rights of Patent Holders
- Certain Limitations of patent rights (familiar flexibilities) and constraints thereof
- Other untapped flexibilities
Rights of a Patent Holder

- Right to **exclude** others from exploiting the invention (TRIPs A28, Kenya-s54, SA-s45) by
  - Making, **importing**, selling, using the invention.
  - Others?

- **infringement**
  - Any other person performing these acts without **owner’s authorization** infringes the patent
Limitations on patents rights

- Constraints in relation to
  - Compulsory licence/government use
  - Exhaustion of rights/Parallel importation
  - Research exemption
Compulsory licensing/Government Use

- **Constraints**
  - Insufficient domestic capacity to produce/knowhow
  - Unviable business
    - Complex/lengthy legal process
    - Price competition with patent holder
    - Availability of subsidized/donated drugs
    - Availability of cheaper alternative drugs
  - Inadequate technical/legal capacity
    - Due diligence wrt the target patents
    - CL necessary?

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Example, Kenya 2004

- Generic producer applied for GU/CL for Zidovudine, lamivudine and Nevirapine.
- Patent holders agreed to give voluntary licences
  - without know how

- Unviable business for Generic producer
  - Voluntary license included expired/unnecessary patents
  - Price competition with patent holders
  - Availability of subsidized/donated drugs
  - Unable to win government tender
Constraint: Lack of information on patent status

Consider CL by Rwanda in 2007
- to import Zidovudine, Lamivudine, Nevirapine
- Was is necessary?
- Patents not identified
Constraints in relation to Exhaustion of rights/Parallel Importation
Exhaustion of rights/Parallel importation

- Constraints
  1. Unclear legal provisions on flexibilities
  2. Misunderstanding/misinterpretation of the law
     - By public and generic producers
     - By courts
  3. Understanding generic drugs
     - What are they?
     - Under what circumstances can they be sold in a market?
  4. Counterfeit and substandard products
Unclear legal provisions: Example

- **S58(2) – Kenya**
  - The rights under the patent shall not extend to acts in respect of articles which have been put on the market in [1] Kenya or in [2] any other country or [3] imported into Kenya.
  - Reg 37: parallel importation (panel beating)
  - The limitation on the rights under a patent in section 58(2) of the Act extends to acts done in respect of articles that are imported from a country where the articles were legitimately put on the market.

- **But query**
  - Putting articles on the market, by who?
  - Patentee impliedly?
  - If so what is the effect of addition/deletion in 2002 of the words “by the owner of the patent or with his express consent.”

- **[3] importation?**
  - Cf s54: query why give and take away?
  - Can a patentee convince the courts to interpret “or” to read “and’’?

- **Legitimately put on the foreign market?**
  - (In case of medicine) not a patent issue but drug authority mandate.
  - How will a Kenyan Court determine? will the court determine compliance with a foreign law?

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Misunderstanding/misinterpretation of the law

- By public and generic producers
- By courts

Example in Kenya

Pfizer v Cosmos (2006)
Pfizer v Cosmos (2006)

- Pfizer: holder of patent no AP 44 wrt Azithromycin dihydrate.
  - Filed on 15/06/1988 (expired in 2008).
  - Cosmos accused of infringing Pfizer patent.
  - Cosmos admitted to have imported, manufactured, stocked and sold the patented product.
- Cosmos relying on s58(2) of IPA and TRIPs
  - argued that it was entitled to deal with the product without the authority of the patent holder.
Pfizer v Cosmos

- Tribunal ruled that:
  - The IPA is founded on TRIPS agreement.
  - TRIPS gives exception (so called flexibilities) which can be exploited by member countries to make use of patented products.
  - The TRIPS exceptions are contained in the IPA as follows:
    - Voluntary license- given by patentee
    - Compulsory license -given by tribunal
    - Government use- by Minister
    - Certain methods of use declared by health Minister as serious health hazard. (only applicable during patent grant procedure).
  - What of S58 (2) and Reg 37. ?

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According to the Tribunal

- **S58(2)** protects acts done by 3rd parties …who are allowed to deal with patented products in any of the exceptions or flexibility.

- “parallel importation… is applicable **for instance where the government** has allowed a third party to exploit the patent, and that party imports the product from other countries where it is legitimately put on the market by way of **some form of license or other legitimate way**. The same argument applies in case of voluntary and compulsory license.”

- “If s58 was interpreted to mean that it provided a blanket protection for anyone to deal with patented products without the patent holder’s authority, then it would defeat the very intention of the Act in the first place.”
According to the tribunal: since Cosmos
- was not licensed by Pfizer;
- had not been granted a compulsory license;
- was not authorized by the government;
- and because it was importing and manufacturing the patented product;

“We are therefore not persuaded that the respondent [Cosmos] can use s58 to legitimize its actions….”

In conclusion, “We find that the respondent did indeed infringe the patent.”

The end justifying the means?
Research exemption

- **Constraints**
  - Inadequate R&D/technical capacity
    - Business venture for generic producers
    - Distinguish commercial purposes/scientific research
      - Would generic producer undertake scientific research while commercial exploitation is prohibited?
  - Weak Linkages between universities and Industry

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Other limitations on patent rights

- Regulatory review (Bolar) exception - TRIPs A30
  - Obtaining of marketing approval prior to patent expiry
  - Immediate market entry at the end of patent term
  - Exploiting the invention remains prohibited

- Term of patent protection - TRIPs A 33
  - 20 years

- Annual fees
Other untapped flexibilities

- Territoriality of patents
- Patent subject matter
- Claims
- Initial patent /improvements
Territoriality of patents

- Patents are granted by national/regional authority in accordance with national/regional laws.
- A Patent granted in one country is not enforceable in another country.
- No single “world patent”…yet!
- No International patent
## IPC:A61K – medicinal preparations

### Published patent applications in various IP Offices*

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** Data accessed from [http://ipindiaservices.gov.in/patentsearch](http://ipindiaservices.gov.in/patentsearch) on 22/01/2013


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Flexibility in relation to patent subject matter

- Distinguishing Product /process patents
- Understanding/interpreting patent Claims
Product vs. process patents

- TRIPs A 27: Product and process patents
- Example: Sildenafil citrate
  - 1993: Compound patent (new medical use)
    - In US (US6469012), EP (EP0702555), ZA (ZA9404018)
    - Not Patented in Kenya/ARIPO
    - Patent status in other African Countries?
  - 1996: Process of preparation patented
    - US5955611, EP0812845, KE/ARIPO(AP717), ZA9705259

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Claims

- define the matter for which protection is sought
- are analogous to real property title deed
- define the scope of protection
  - i.e. the territory under the control of the inventor
  - suing in case of infringement.

- **Constraints**
  - Understanding /Interpreting the claims

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Initial patent /improvements

- Substantial number of initial patents not filed in African Countries
  - They can be exploited freely
  - Territoriality

- However improvement patents filed

- Consider expired initial patents vs. improvement patents.

- Constraints
  - Lack of information on patent status
  - Capacity to provide such information

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Example 1: Azithromycin (antibiotic)

  - Patent not filed in Kenya/ARIPO.
  - ZA? Other African Countries?
  - Azithromycin Dihydrate- a new form of Azithromycin
  - Problem/solution: hygroscopic/new form- non hygroscopic

- 06/04/1995: AP 566 (in force until 05/04/2015)
  - Oral dosage forms of azithromycin
  - Problem: Azithromycin absorption affected by food.
  - Solution: new dosage form which does not exhibit adverse food effect

- 31/07/2002: AP 1729 –(in force until 30/07/2022)
  - Single dose azithromycin

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Example 2: CLOPIDOGREL

- **Plavix®** (for prevention of blood clots)
  - Initially disclosed by US patent 4847265, Filed 12/2/1988
    - Patent not filed in Kenya/ARIPO
    - ZA? Other African Countries?
  - **AP 1344** - Filed 10/06/1999 (in force until 2019)
    - Form II Clopidogrel hydrogen sulphate
    - Problem/solution:
      - improved stability, better physical properties & new preparation procedure
  - **KE 523** –Filed 18/04/2005 (17/04/2025)
    - Polymorphic forms A-F of clopidogrel acetate hydrochloride
Others

- **Perindopril**, 1980 (For hypertension)
  - Initial patent not Filed in Kenya/ARIPO
  - Patented in ZA

- **Omeprazole**, 1978 (for treatment of ulcers)
  - Initial patent not Filed in Kenya/ARIPO
  - Patented in ZA
End

Thank You

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