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?

Compulsory licensing/Government Use

- Example, Kenya 2004
  - Generic producer applied for GU/CL for Zidovudine, lamivudive 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

Compulsory licensing/Government Use

- 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.
  - [1] domestic exhaustion and [2] international exhaustion
- **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?

- 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. ?

Pfizer v Cosmos

- 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."

Pfizer v Cosmos

- 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

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*

Publication year	US	CN	EP	AU	ZA	BR	IN**	KE***	AP	EG
2012	19,360	28,552	10,298	4,229	-	819	397	65	42	23
2011	21,308	21,713	12,508	2,691	-	1,127	452	66	43	29
2010	23,534	19,791	10,837	2,475	1420	1,127	694	62	28	26
2009	22,670	18,669	10,711	4,891	1971	1,048	1315	28	38	62
2008	20,301	18,572	12,085	5,841	2190	2,015	1463	28	41	104

*Data accessed from espacenet http://worldwide.espacenet.com on 22/01/2013
** Data accessed from http://ipindiaservices.gov.in/patentsearch on 22/01/2013
*** published/unpublished Patent applications(excluding ARIPO publications) accessed from KIPI database.

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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

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

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

Example1: Azithromycin (antibiotic)

- 15/11/1982: Azithromycin initially disclosed in US 4474768
  - Patent not filed in Kenya/ARIPO.
  - ZA? Other African Countries?
- 15/8/1988: AP 44 (expired on14/08/2008)
  - Azithromycin Dihydrate- a new form of Azithromycin
  - Problem/solution: hygroscopic/new form- non hygroscopic
- 06/04/1995: AP566 (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

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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