Advanced Course for Justices Handling Commercial Matters

Compulsory Licensing in Pharmaceutical Patents

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Patents – *Quid Pro Quo*

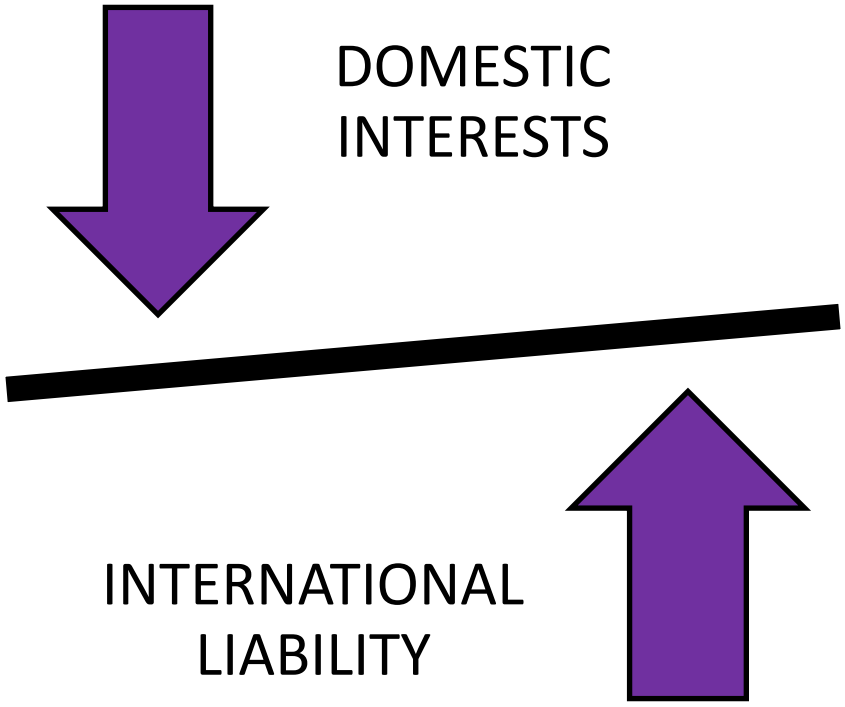
"Patent is an award for the inventor and a reward for the investor".

- Incentive for inventors to **disclose** their invention to general public which may otherwise have remained secret
- in exchange for a limited right granted by the government to **exclude** any other person from practicing the invention, without due permission.

Milestones - Legislative History of Patents in India

- 1857 to 1872 – initial developments - The Patterns and Designs Protection Act" under Act XIII of 1872
- The Indian Patents and Designs Act, 1911
- Amended in 1950 (Act 32 of 1950) - Justice (Dr.) Bakshi Tek Chand Committee recommendations
- Ayyangar Committee report - 1959
- The Patents Act, 1970 (39 of 1970)
- India joined WTO and TRIPS (Trade-Related Aspects of Intellectual Property Rights) in 1995
- Requests for 10 year transition period for compliance
- 1970 Act amended in three stages:
  - The Patents Amendment Act, 1999 (effective 1.1.1995)
  - The Patents Amendment Act, 2002 (effective 1.1.2000)
  - The Patents Amendment Act, 2005 (effective 1.1.2005)

Balancing Act



India allows
Product patents
– **the 2005 Act**

Right of inventor vs. Public interest

- Why the debate around pharma
- Economic realities
- Healthcare facilities by Government
- Government budget for healthcare
- Patient Access Programs
- Deadly cocktail:
  - Largest patient pool
  - No insurance
  - Largest generic manufacturer

Compulsory Licensing (CL) of Patents

- License by the government to allow a third party to produce the patented product or process without the consent of the patent owner
- Introduced in Paris Convention, 1883 (Art. 5A) to prevent abuse of exclusive rights conferred by patent
- One of the flexibilities on patent protection included in the WTO's agreement on intellectual property — the TRIPS Agreement (Art. 30 and 31)
- Doha Declaration of 2001 (Para 6)
- Several countries have granted CL in public interest

CL granted by other countries

Country	Year	Key Highlights of Compulsory Licensing	Income Group as per GNI Per capita* (Development status)
Zimbabwe	2003	Issue compulsory license to a local generic company- Varichem Pharmaceutical Co. to produce seven generic versions of first line Anti Retroviral Drugs (ARVs).	Low Income
Malaysia	2004	Issue compulsory license to import generic version of Anti Retroviral Drugs (ARVs) from Cipla (India) for 2 years.	Upper middle Income
Indonesia	2004	Indonesia first issued a presidential decree to use compulsory license for two ARVs – lamivudine and nevirapine.	Lower middle Income
	2012	Indonesia issues compulsory licenses against seven HIVs, Hepatitis drug include efavirenz, abacavir, tenofovir, lopinavir/ritonavir, didanosine, and fixed-dose combinations tenofovir/emtricitabine and tenofovir/emtricitabine/efavirenz citing urgent need to improve patient access.	
Mozambique	2004	Issue compulsory license to Pharco Mozambique Ltd. for HIV/AIDS drugs.	Low Income
Zambia	2004	Issue compulsory license to Pharco Ltd., a local producer, production of triple fixed-dose combination for Anti Retroviral Drugs (ARVs) drug.	Lower middle Income
Ghana	2005	Issue compulsory license for import of generic Anti Retroviral Drugs (ARVs).	Lower middle Income
Eritrea	2005	Issue compulsory license to import generic HIV-AIDS medicine from India.	Low Income
Thailand	2006	Issue compulsory license to import generic and locally produce Efavirenz from India.	Lower middle Income
	2007	Issue compulsory license to the heart disease drug Plavix (Clopidogrel bisulphate) and for AIDS drug Kaletra. (LPV+RTV).	

Brazil	2007	Issue compulsory license to import generic efavirenz from India rather than buy Stocrin – the brand name for patented efavirenz – from its US-based manufacturer Merck & Co.	Upper middle Income
Rwanda	2007	In 2007, Rwanda issued a compulsory license for TriAvir (a combination of Zidovudine, Lamivudine and Nevirapine used to treat HIV/AIDS) that it could not produce locally and applied for assistance from Canada.	Low Income
Ecuador	2009	Compulsory licenses were issued by the national Ecuadorian Institute of Intellectual Property (IEPI), and the term of application of the license for ritonavir/lopinavir.	Upper middle Income
	2012	Issue compulsory license for abacavir/lamivudine.	
India	2012	Issue compulsory license to Natco for Bayer's drug Nexaver.	Lower middle Income

Compulsory Licensing of patents in India

Section	Time	Ground	Who can apply
Section 84	Any time after three years from the date of grant of the patent.	i) Reasonable requirements of the public with respect to the patented invention have not been satisfied or ii) The patented invention is unavailable to the public at a reasonably affordable price or iii) The patented invention is not worked in the territory of India.	Any interested person
Section 92	Any time after grant of patent	i) A national emergency ii) Circumstances of extreme urgency iii) Public non-commercial use	Upon declaration by the Central Government, any interested person
Section 92A	Any time after grant of patent	Under certain exceptional circumstances (in line with Paragraph 6 of the Doha Declaration on TRIPs and Public Health), a compulsory license can be granted to a country to manufacture and export patented pharmaceutical products with insufficient or no manufacturing capacity in the pharmaceutical sector in order to address public health issues.	

Section 84(1)

- **Reasonable requirements of the public not met – *s. 84(7)***

- Several statutory circumstances listed including:

  - Trading or manufacturing in India jeopardized
  - Demand for patented article not met adequately
  - Market for export of article not being developed/supplied
  - Establishment/development of commercial activities in India is prejudiced
  - **Patent not being worked commercially to a reasonably practicable/adequate extent in territory of India**
  - If working on a commercial scale in the territory of India is hindered by importation from abroad by patentee or his collaborators

Section 84(1)

- **Not available to the public at a reasonably affordable price**

- **“Reasonable”** and **“affordable”**:
  - Is there an interplay
  - Can a benchmark be practically set
  - Expenses on R&D and patent to be kept in mind while deciding “reasonable” royalty *(basis – Ayyangar Committee Report)*

Section 84(1)

- **Patented invention <u>not worked</u> in the territory of India**

  - A CL may be granted if the patented invention is not worked in the territory of India *(s.84(1)(c), s. 84(4))*
  - Reasonable requirement of the public will not be satisfied if the patented invention is
    - **not being worked** in the territory of India
    - **on a commercial scale**
    - to an **adequate extent** <u>or</u>
    - is not being worked to the **fullest extent** that is **reasonably practicable** ***(s. 84(7)(d))***

General statutory principles applicable to working of patented inventions (s.83)

- Encourage inventions
- Working in India on commercial scale; make invention available at reasonably affordable prices to public
- Check monopoly by mere importation
- Promotion, transfer and dissemination of technological innovation
- Mutual advantage of producers and users
- Balance of rights and obligations; social and economic welfare
- patents to act as instruments of public interest – not to be abused by patentee

Working information

- Patentee/Licensee required to furnish:
  - Statement regarding:
    - Working: quantum and value (in Rupees) of the patented product
    - Non-working : reasons therefor, steps being taken
  - Licenses and sub-licenses granted during the year
  - Statement regarding whether public requirement has been met partly/adequately/to the fullest extent at reasonable price
  - Undertaking that the disclosure is to the best of the knowledge, information and belief of the Patentee/Licensee submitting this information

Penalties

❑ Non-compliance of s. 146

a) Failure to supply information – Fine up to ten lakh rupees

b) Giving false information- Fine or imprisonment up to six months, or both

In *[Franz Xaver v Yash Engineers* (AIR 1977 Delhi 79)*;*

Sandeep Jaidika v Mukesh Mittal and Anr (2014 (59) PTC 234 (Del) and *Glaverbel S.A. vs. Dave Rose and Ors.,* 2010 (43) PTC 630 (Del)*]*

- interim injunction in infringement proceedings was denied since the Court found there was ***no working of the patent at all***

Natco's attempt for CL under s. 92A

- In 2007, Natco tried to seek CL under s. 92A for Roche's Tarceva and Pfizer's Sunitinib citing public health problem in Nepal
- Several deficiencies in the application including lack of proper documentation permitting import by Nepal government
- Applications withdrawn by Natco in 2008

Bayer vs. Natco – the Nexavar case

" 'Compulsory licence' is not an unmentionable word. It is found in our Patents Act. Under a different name, it was there in the TRIPS (Trade-related Aspects of Intellectual Property Rights) too where it is called, 'Other use without authorization of the right holder'…".

"We must bear in mind that these proceedings are in public interest; they are neither against the inventor, nor in favour of the compulsory licensee."

[***Bayer Corporation v UOI and Ors; IPAB***; Order No. 45/2013]

Bayer vs. Natco – the Nexavar case

- SORAFENIB TOSYLATE (palliative kidney cancer drug) covered by Bayer's patent
- Compulsory License issued by CG IPO to Natco based on following:
  - **AVAILABILITY:** Only insignificant quantum of drug made available to the public (the drug was accessible only to a little above 2% of eligible patients)
  - **AFFORDABILITY: INR 2,80,428/-** per month compared to **INR 8800/-** per month proposed by Natco.
  - **WORKING:** Mere importation - hence not worked in India.
  - Royalty rates increased by IPAB from 6% to 7%; held whether importation constitutes working needs to seen on case to case basis
  - High Court upholds the CL and agrees with IPAB

- *Natco Pharma Limited vs. Bayer Corporation CLA No. 1 of 2011, decided March 9, 2012 IPO*
- *Bayer Corporation vs. UOI & Ors. OA/35/2012/PT/MUM decided March 04, 2013 IPAB*
- *Bayer Corporation vs. UOI & Ors. Writ Petition No.1323 OF 2013 decided July 15, 2014 Bom HC*

BMS vs BDR Lifesciences

- BDR filed an application for CL before the Controller;
- BDR CL application rejected by the Controller – No *prima facie* case made out since BDR failed to show reasonable attempts to obtain VL from BMS – Did not answer BMS queries;
- BMS also filed a *quia timet* suit against BDR and obtained interim injunction;
- No appeal – settlement application moved

BMS fought back against CL with data

- RTI used to enquire from various hospitals regarding the requirement of DASATINIB,
- market survey conducted and
- expert opinions regarding demand obtained
- Patient Access Program (PAP)

The Court considered all these aspects and denied the allegation of the Defendants that the patented invention is not worked in India.

Bristol-Myers Squibb Company & ors v J.D. Joshi; CS(OS) 679 of 2013; High Court of Delhi

Astrazeneca vs Lee Pharma

- Lee Pharma filed an application for the grant of CL for Saxagliptin covered by IN 206543 which belongs to Astrazeneca (Assigned from BMS)
- The Patent Office has notified that application does not *prima facie* qualify consideration
- Applicant alleged
  - drug available to only 0.23% patient pool (assuming all Type II patients in India need this drug)
  - Patentee earning high percentage of profit – cost per tablet excessively high (Rs. 41-49 as against Rs. 27-32 proposed by applicant)
  - Not being locally manufactured
- Applicant has moved request for hearing and case is in progress
  - Patentee also filed an infringement suit against Lee Pharma

Some key questions…

- How affordable is affordable
- What kind of medicines warrant CL u/s 84
- Government help/subsidy
- Accessibility channels
- Robust PAP programs
- Who monitors working
- India's standing in the International space
- Filing of patent applications including pharma in India skewed heavily towards foreign applicants
- Will public interest issues lead to patents being paper tigers

Q&A