

Flexibilities before the grant of a patent

Introduction to patentability criteria and flexibilities

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WHO-SEARO**

Patent and Public Health Concerns

- Access to medical products- product v process patent
- TRIPS Art 39.3 Data protection “unfair commercial use” –no duration for data protection specified
- ‘adequate remuneration’ for patent owner in compulsory licensing
- Free trade agreements

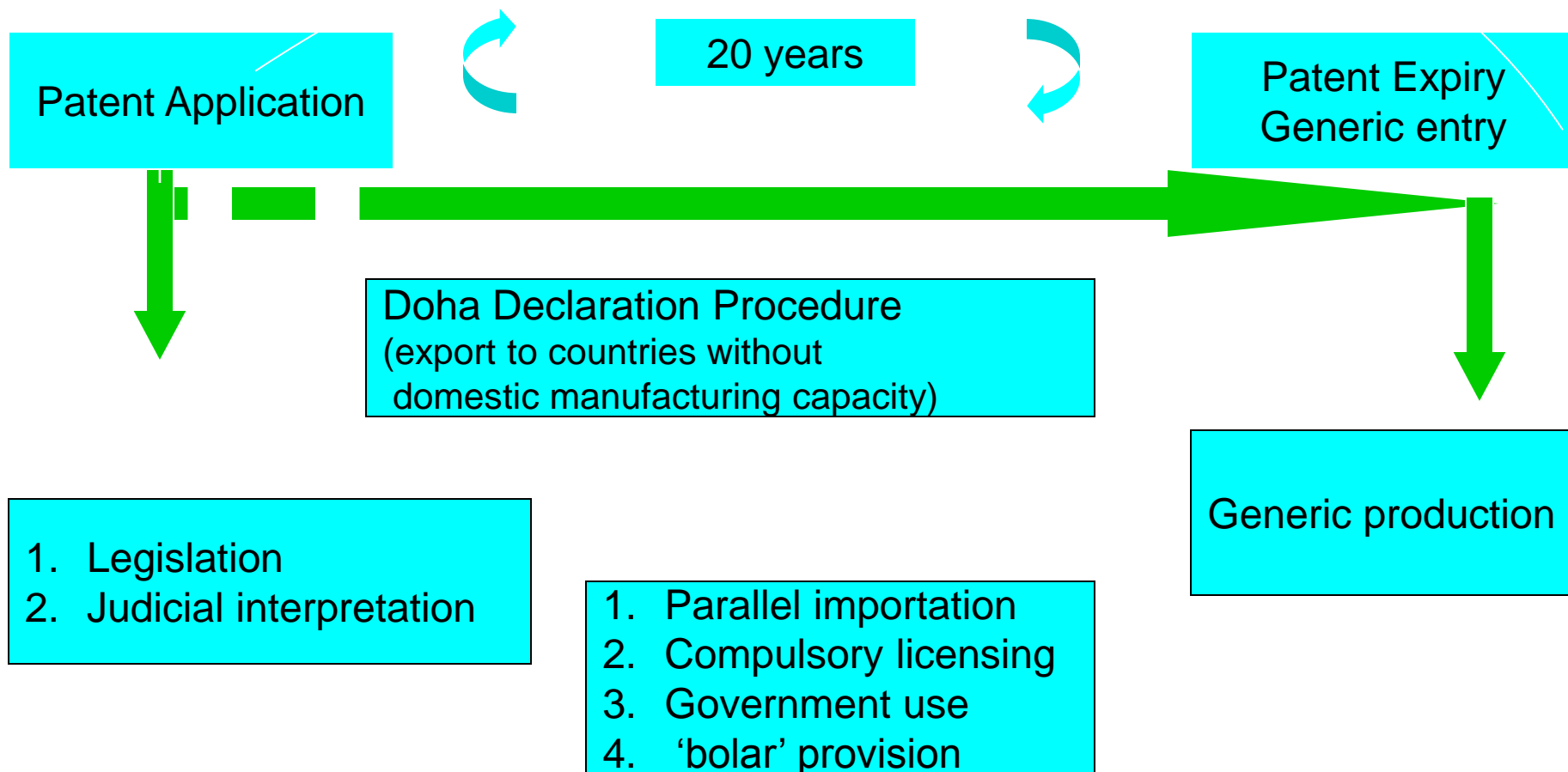
Patent

A patent is an exclusive right granted for an invention that allows an owner to license others to use the invention often for commercial gain.

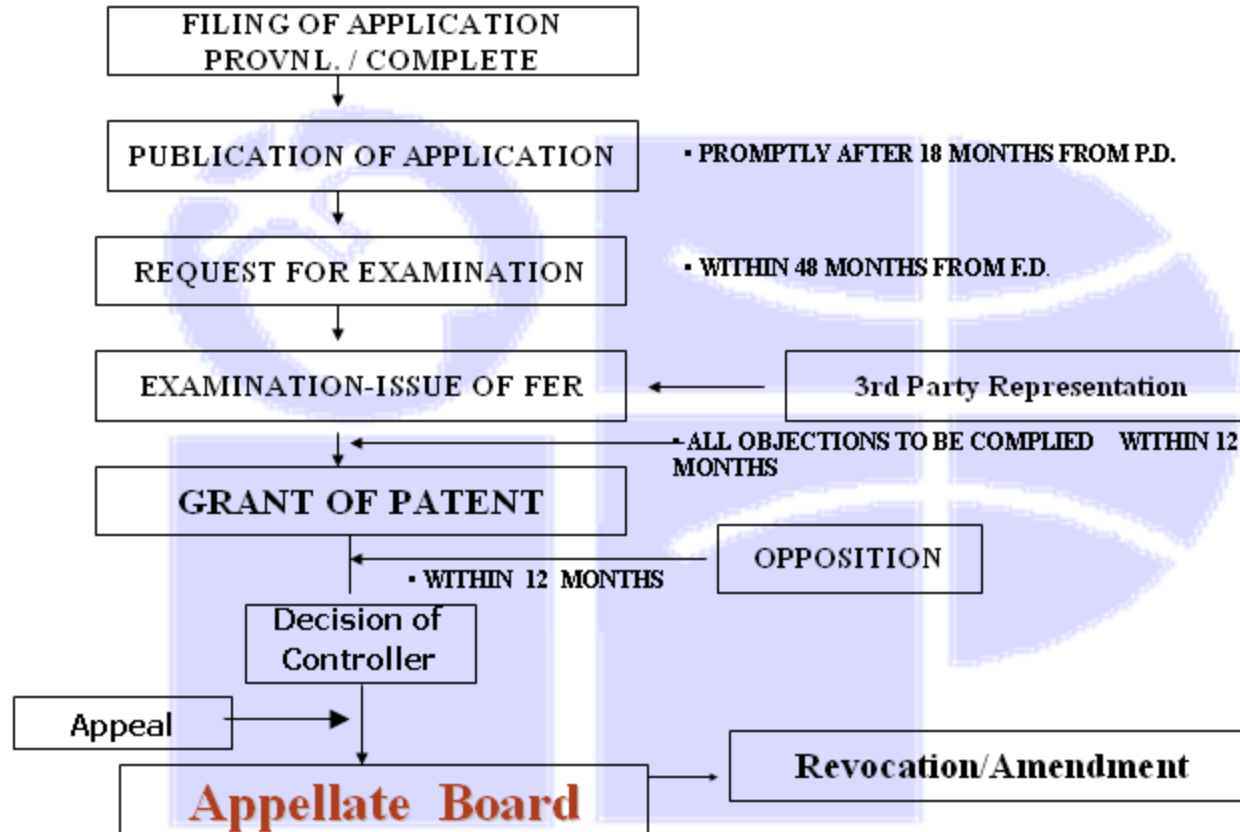
- New
- Inventive Step
- Industrially Applicable

- Written description, enablement, best mode

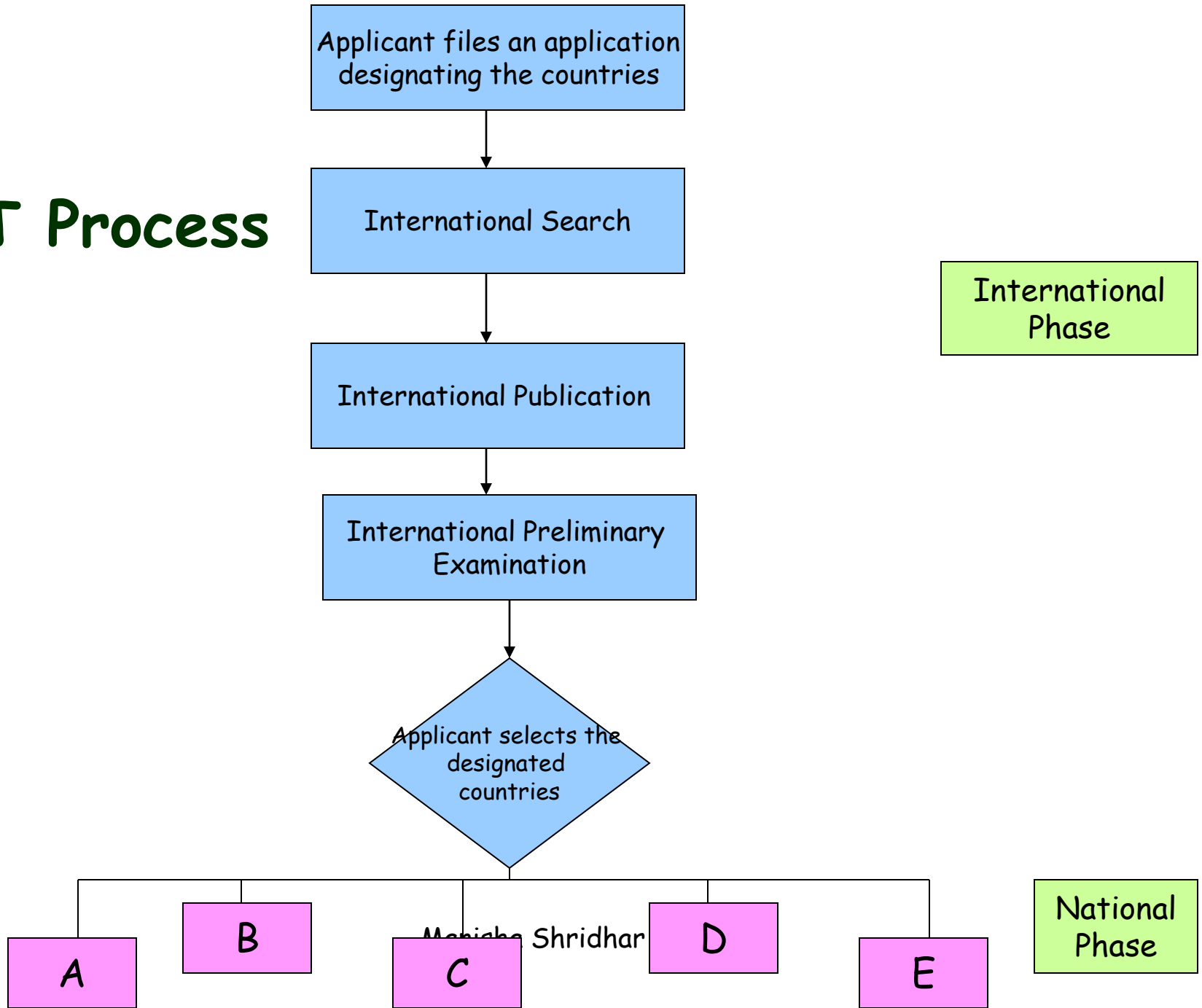
Flexibility in Patenting vs Patent Flexibilities



STAGES - FILING TO GRANT OF PATENT



PCT Process



TRIPS and the DSB

- Complaint by U.S. & E.U. Patent Protection for Pharmaceutical & Agricultural Chemical Products--DSB meeting on 28 April, 1999-India reports enactment of relevant legislation
- Has territorial Application
- 1st WTO Agreement to lay down domestic enforcement provisions
- Transitional Periods:

Developed countries	1.1.1996	Developing countries
1.1.2000	(In case patent protection is not available to an area of technology up to 1.1.2005	subject to mail box and EMRs
- No transitional period for MFN & National treatment

TRIPS : Doha Declaration 30th August 2003

(a) the eligible importing Member(s) (4) has made a notification (2) to the Council for TRIPS, that:

- (i) specifies the **names** and expected **quantities** of the product(s) needed (5);
- (ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has **insufficient or no manufacturing capacities** in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and
- (iii) confirms that, where a pharmaceutical product is patented in its territory, it has **granted or intends to grant a compulsory licence** in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision (6);

TRIPS : Doha Declaration 2

the compulsory licence issued by the exporting Member shall contain the following conditions:

- (i) only the **amount necessary** to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the **entirety of this production shall be exported** to the Member(s) which has notified its needs to the Council for TRIPS;
- (ii) **products produced** under the licence shall be clearly **identified** as being produced under the system set out in this Decision through specific **labelling or marking**. (iii) before shipment begins, the licensee shall post on a website (**7**) the following information:
- (c) the **exporting Member shall notify (8) the Council for TRIPS of the grant of the licence, including the conditions attached to it (9)**. The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

TRIPS : Doha Declaration 3

- adequate **remuneration** pursuant to Article 31(h) of the TRIPS Agreement shall be paid
- reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to **prevent re-exportation** of the products that have actually been imported into their territories under the system.
- Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America

Grounds of Opposition in Indian Law Sec 25

1. Patent is wrongfully obtained
2. Prior publication in any document anywhere in the world
3. Prior claiming and publication in India
4. Prior public use in India
5. Obviousness-no inventive step
6. Not an invention u/s 2(i)(J) or is not patentable under the Act.
7. Insufficiency of description
8. Failure to disclose information regarding corresponding foreign applications
9. Conventional application not filed in India within 12 months from the date of filing in conventional country.
10. Wrong or no disclosure of the source or geographical origin of the biological material used in the invention;
11. Invention belongs to traditional knowledge

Continuous Evolution of Patent Law

● Developed Nations

- **Switzerland** 1888 (mechanical model) - 1905 (chemical)
- **US** 1789 US Constitution Art 1 Cl 8 Sec 8
 - 1790-1st patent act
 - 1793 modification for defining patent
 - 1952 modern law
 - 2012 AIA
- 1930 - Plant Patent Act established, which allowed asexual, manmade plants to receive patents.
- 1946 – In order to receive a patent one had to be the “first to invent,” in the world. This was amended to “first to invent” within the US. (*Storage Battery v. Shimadzu*)
- 1994 Uruguay Round Agreements Act the length of a patent was changed from 17 years after being granted to 20 years after application.
- 1998 – *State Street Bank v. Signature Financial*: Federal Circuit rules an eligible invention must produce "a useful, concrete and tangible result."¹
- 2008 – *In re Bilski*, Federal Circuit invention must “transform an article to a different state or thing”, State Street test not to be relied upon 2009 – *In re Bilski*, Supreme Court

American Invents Act 16 September 2011

U.S. Patent and Trademark Office (USPTO)

- American Invents Act 16 September 2011
 - procedures for post-grant review proceedings after September 16, 2012) and a change to a first inventor to file system (after March 16, 2013)
- **Proceedings Before the USPTO**

A limitation on the issuance of claims directed to or encompassing a human organism after, September 16, 2011.
- **Reexaminations Before the USPTO**

The standard for the Director to grant an inter partes reexamination will change on September 16, 2011 from the current standard requiring a requestor to show a “substantial new question of patentability” to a new standard requiring a requestor to show “that there is a reasonable likelihood that the requestor would prevail with respect to at least 1 of the claims challenged in the request.” See Sections 6(c)(3)(A) and (B) of H.R. 1249.

Judicial decisions

- patents on two breast cancer genes held by Myriad Genetics: BRCA1 and BRCA2: cancer screening tests
- **lundi 10 octobre 2011** : T1685/10 : il faut prouver l'effet thérapeutique : Le brevet en cause avait pour objet l'utilisation d'inhibiteurs RAS spécifiques pour fabriquer un médicament destiné à traiter ou prévenir les (accident vasculaire cérébral) AVC chez les patients humains.

Influencing legal climate for accessibility: Arbitration

- 1985 UNCITRAL Model Law on International Commercial Arbitration –choice of law
- Dispute between two drug companies over intellectual property rights under their collaboration agreement was arbitrable Pharmacia & Upjohn Co. v. Elan Pharmaceuticals, Inc., 10 A.D.3d 331, 781 N.Y.S.2d 95
- Where a party obtained a stay of an action, in order to permit arbitration, and thereafter refused to initiate arbitration ----he waived the right to arbitration. Zuber v. Commodore Pharmacy, Inc., 24 A.D.2d 649, 262 N.Y.S.2d 155 (2d Dep't 1965) [FN 3]

Developing Roadmaps by 2015- Access for Medical Products Conclusions

- Safety, efficacious, reliability and affordability issues for all countries-1995 to 2012
- Distinguishing patentability criteria from flexibilities
- International level Doha mechanism— WTO
- National level
 - Legislative
 - Judicial
 - Regulation
- Legal persons obligations-Competition/Alternative Dispute Settlement

THANK YOU