सत्यमेव जयते
Department of Industrial Policy and Promotion
Ministry of Commerce and Industry
Government of India

INTELLECTUAL PROPERTY INDIA

Public Health and Intellectual Property

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Patents and the TRIPS Agreement

- **Minimum standards for patent protection** for protection and enforcement of intellectual property with a view to reducing distortions and impediments to international trade.
- **Framework for national implementation** but not a **uniform international law** or uniform legal requirements
- Patents to protect ***inventions***, in **all fields** of technology
- **Patentability criteria**: novelty, inventive step, industrial application **(TRIPS Art.27)**
- Patents for both **products and processes**
- Patent **Term** – minimum of **20 years**
- Patents and the promotion of **public interest**

TRIPS FLEXIBILITIES

TRIPS Article- 30
Exceptions to rights conferred

- Limited exceptions to the exclusive rights conferred by a patent
- provided that such exceptions do not **unreasonably conflict** with normal exploitation of the patent and **do not unreasonably prejudice the legitimate interests of the patent owner**, taking account of the legitimate interests of third parties.

Specified and limited use of patent permitted

- "**Bolar**" **PROVISION:** Use of patent prior to expiry for approval for generic product for report to the regulatory authority,
- **Other uses:** research, experimental**,**
- **Not defined,** Automatically applicable if provided for in legislation, no further conditions

TRIPS Article 31
Other Use Without Authorization of the Right Holder

- **Public non-commercial (Government) Use** - **Government right** (Govt. agency, dept. or contractor) **to use patent in the public interest**
- **Compensation** to patent holder
- Scope and duration **limited to the purpose**

➢ Compulsory licence:

- Government can grant licence to third party to use patent **without consent of patent holder.**
- **Conditions for grant:** prior negotiations, compensation to patent holder, appeals process
- **Non-exclusive, non-assignable**, authorized predominantly for supply to domestic market **[31(f)].**
- **Liable to be terminated** when the circumstantial need ends excepting to prevent anti-competitive practice determined after judicial or administrative procedure
- To correct the anti-competitive practice, the judicial authority may refuse termination.

TRIPS and Amendments to Indian Patents Act

India became a **member of the TRIPS effective January 1, 1995** and became obligated to amend its domestic IPR laws in compliance with TRIPS Agreement.

- India got **grace period (10 yrs)** till 2005 to amend its laws to be TRIPs compatible
- Accordingly, **Amendment** of Patents Act 1970 was done in **3 stages**: **1999, 2002 and 2005 amendments.**
- **Patents (Amendment) Act, 1999** was brought into force from **1st January, 1995**.

The Amended Act provided for **filing of applications for product patents** in the areas of drugs, pharmaceuticals and agro-chemicals as **Mail-box applications,** though product patents were not allowed. Such applications were **to be examined only after 31-12-2004.**

- Meanwhile, the applicants could be allowed **Exclusive Marketing Rights (EMR)** to sell or distribute these products in India, subject to fulfilment of certain conditions.
- **The Second amendment** was made through the Patents (Amendment) Act, **2002** .
- **The Third amendment** was introduced through the Patents (Amendment) **Ordinance, 2004 w.e.f. 1st January, 2005., which was l**ater replaced by the **Patents (Amendment) Act 2005 on 4th April, 2005**, brought **into force from 1-1-2005.**

Salient features of the Patents (Amendment) Act, 2002

- C**odification of non-patentable inventions**
- **20 years term** of patent for all technology
- Provisions of **compulsory licences** to meet public health concerns
- Deletion of provision of **licence of right**
- Introduction of system of **Deferred Examination**
- **Mandatory publication** after 18 months from the date of filing
- Establishment of **Appellate Board**
- **Burden of proof in case of suits concerning infringement** [S. 104-A]: Burden of Proof is on the defendant provided that patentee first proves that the process that has produced a product so desired, is identical to be patented products .
- Provision for **parallel imports**
- No infringement proceedings for use of a patented invention for obtaining **regulatory approval for a patented product**
- Provision **to protect biodiversity and traditional knowledge**
- ***Compliance with Budapest Treaty:*** Deposit *of biological material* for completing the disclosure to be made before the date of filling and reference to be given in the application. Access to material available upon publication

Patents (Amendment) Act 2005

- Extension of **product patents** to all fields of technology including food, drugs, chemicals and micro organisms
- Deletion of the provisions relating to **Exclusive Marketing Rights**
- Introduction of a provision of **compulsory licence for export of medicines** to countries having insufficient or no manufacturing capacity to meet emergent public health situations
- Modification in opposition procedures by having **both pre-grant and post-grant opposition** in the Patent Office
- Strengthening the provisions relating to national security to guard against **patenting abroad** of dual use technologies
- Rationalisation of **provisions relating to time-lines** with a view to introducing flexibility and reducing the processing time for patent application

Public Interest Provisions in Patents Law

- **No ever greening:**
  - No patent for a new use of a known drug or substance **: (Section 3d):**
- **Revocation of Patent by the Government in public interest: (Section 66)**
- **Bolar provison** : To facilitate generic version of the patented product at competitive prices immediately on expiry of the patent: **(Section 107(a)).**

  Compulsory licences : Availability of products at reasonable price ensured : (Section 84)

  Special Provision of Compulsory license during national emergency, extreme urgency or public non-commercial use : (S. 92).

  Use and acquisition of patents by Government for public purpose : Compensation by mutual agreement between the Government and patent holder, failing which by the High Court: (Section 102)

Unique legislative provisions in Indian IPR laws

Non- patentable Inventions (Section 3)

- **Inventions contrary to Public order / morality**
- **Discoveries are not patentable (living/non–living substance occurring in nature.**
- **Methods of Agriculture or Horticulture**
- **Methods of treatment for human beings *or* similar treatment of animals to render them free of disease *or* to increase their economic value**
- **Plants & animals *in whole or any part thereof other than* micro- organisms, *but* including seeds, varieties and species *and* essentially biological process for production or propagation of plants & animals.**
- **A mathematical method or a business method or Algorithms or Computer programme *per se.***
- **An invention which, in effect, is the Traditional Knowledge or an aggregation or duplication of known properties of traditionally known component or components**

Section 3 (d)

Patents (amendment) Act 2005 introduced **section 3 (d) along with explanatory part** stating that the **incremental inventions** like polymorphs etc. to be treated as same substance unless an improved efficacy is established.

Section 3 (d) :

*The **mere discovery** of a **new form** of a known substance which does not result in the enhancement of the known efficacy of that substance **OR** the mere **discovery** of any **new property or new use for a known substance OR** of the **mere use of a known process**, machine or apparatus, **unless such known process results in a new product or employs at least one new reactant**.*

Explanation : For the purposes of this clause,:

*Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixture of isomers, complexes, combinations and other derivatives of known substances, shall be considered to be the **same substance, unless they differ significantly in properties with regard to efficacy**.*

Novartis case

- The matter was taken to Supreme Court by Novartis AG against rejection of their patent application. The product involved is beta crystalline form of imatinib mesylate, used to treat chronic myeloid leukemia and is marketed by Novartis as “Glivec”. Novartis challenged the rejection of the patent application as well as validity of section 3 (d) through the appeal.
- **The Hon’ble Supreme Court decided all the issues on 1st April 2013 in the landmark decision in this case , dismissing the appeal and upholding the validity of section 3 (d).**
- **The Court clarified that efficacy as contemplated under Section 3(d) is therapeutic efficacy**.
- **The Court stated , inter alia, in their decision:-**

Novartis Case Decision

- *"We find no force in this submission that section 3(d) is a provision ex majore cautela (Out of abundant caution).. To our mind, the submission completely misses the vital distinction between the concepts of invention and patentability – a distinction that was at the heart of the Patents Act as it was framed in 1970, and which is reinforced by the 2005 amendment in section 3(d).* [Paragraph 102]
- *" We have, therefore, no doubt that the amendment/addition made in section 3(d) is meant especially to deal with chemical substances, and more particularly pharmaceutical products. The amended portion of section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds.* [Paragraph 103]

Novartis Case Decision

"While dealing with the explanation it must also be kept in mind that each of the different forms mentioned in the explanation have some properties inherent to that form, e.g., solubility to a salt and hygroscopicity to a polymorph. These forms, unless they differ significantly in property with regard to efficacy, are expressly excluded from the definition of "invention". Hence, the mere change of form with properties inherent to that form would not qualify as "enhancement of efficacy" of a known substance. In other words, the explanation is meant to indicate what is not to be considered as therapeutic efficacy". [Paragraph 181]

"We have held that the subject product, the beta crystalline form of Imatinib Mesylate, does not qualify the test of Section 3(d) of the Act but that is not to say that Section 3(d) bars patent protection for all incremental inventions of chemical and pharmaceutical substances. It will be a grave mistake to read this judgment to mean that section 3(d) was amended with the intent to undo the fundamental change brought in the patent regime by deletion of section 5 from the Parent Act. That is not said in this judgment". [Paragraph 191]

4. Pre-grant opposition [S.25(1)]

Any person may file opposition to grant of patent, before grant of patent but after publication of Application, along with Statement and supporting evidence, if any, and may request for hearing , if so desired.

Grounds for Pre Grant Opposition:

A) Patent is wrongfully obtained

B) Prior publication in India or elsewhere

C) Prior claiming

D) Prior public knowledge or use

E) Obviousness

F) Not an invention or not patentable under the Act

G) Insufficient and unclear description or method of working

H) Failure to disclose or falsely furnishing the information on corresponding foreign filing

I) Conventional application filing late

J) Source or geographical origin of biological material used for the invention - not disclosed or wrongly mentioned

K) Invention anticipated by the knowledge,oral or otherwise, available within any local or indigenous community in India or elsewhere

COMPULSORY LICENCES

- May be granted after 3 years from the date of grant of patent on failure to work a Patent, to any Interested party to work the Patented Invention (S. 84)

GROUNDS

- Reasonable requirement of the public has not been satisfied with respect to the patented Invention or.
- Patented Invention is not available to the public at a reasonable price or
- Patented Invention is not worked in the Territory of India
- At any time after grant of the patent , Central Govt. can direct the Controller to grant compulsory license to any interested party, in the circumstances of :

  - ❖National emergency
  - ❖ Extreme urgency
  - ❖ Public non- commercial use

Revocation of the patent in the public interest

Provided under section 66, which states that-

- *" Where the Central Government is of the opinion that a patent or its mode of exercise is mischievous to the state or generally prejudicial to the public, it may, after giving the patentee an opportunity to be heard, make a declaration to that effect in the official Gazette and thereupon the patent shall be deemed to be revoked".*

- **No Infringement Provisions (S.104)**

Any act of making , using or selling a patented invention solely for uses reasonably **related to the development and submission of information required** under any law for the time being in force ,in India or in any other country **that regulates** the manufacture, construction use or sale of any product.

Parallel Import (S.107 A)

Importation of patented products by any person from a person who is duly authorised by the patentee to sell or distribute the product

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THANKS!