COMPULSORY LISCENCE

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- The Patents Act, 1970 was amended three times in
  - **1999**
  - **2002**
  - **2005** respectively
- to include the concept of **‘compulsory license’**

- compulsory licenses are **authorizations given to a third-party by the Government** to
  - make, use or sell a particular product or
  - use a particular process
  - which has been patented,
  - without the need of the permission of the patent owner

- The provisions regarding compulsory licenses are given in
  - the Indian Patents Act, 1970
  - the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement at the International level.
- this works against the patent holder
- compulsory licenses are only considered in certain cases of **national emergency, and health crisis**
- There are certain **pre-requisite conditions** which need to be fulfilled if the Government wants to grant a compulsory license in favor of someone

- Under Indian Patents Act, 1970 the provisions of ‘compulsory license’ are specifically given under Chapter XVI
- conditions which need to be fulfilled are given is Sections 84-92 of the said Act.

Section 84

- At any time **after the expiration of three years** from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely:
  - That the **reasonable requirements of the public** with respect to the patented invention have **not been satisfied**, or
  - that the **patented invention is not available to the public at a reasonably affordable price**, or
  - that the patented invention is **not worked in the territory of India**

- Any person who is interested or already the holder of the license under the Patent
- can make a request to the Controller
- for grant of compulsory license
- on expiry of the three years,
- when the conditions are fulfilled

- compulsory licenses may also be granted, when –
- **Section 92 A-** For exports, under exceptional circumstances
- **Section 92A-** In case of national emergency, extreme urgency of public non-commercial use by notification of the Central Government
- **Section 92 A (1)** – To a country which has insufficient or no manufacturing power in the pharmaceutical sector to address public health

Aim

- The Compulsory license provisions is aimed at **curbing the practice of meeting the demand for patented articles solely by importation from abroad thereby discouraging:**
  - transfer of technology,
  - development in existing trade & industry,
  - non-establishment of new trade & industry,
  - refusal to grant licenses to work the patent locally,
  - imposing unreasonable terms on licenses thereby discouraging voluntary licensing and imposing restrictive conditions on the use,
  - sale or lease of the patented articles thereby prolonging the patent monopoly rights even after the patent has expired.
  - Revocation of the patent for non-working has been adopted in almost all countries.

Controller

- In considering the application for the grant of compulsory license, the Controller shall take into account
  - the nature of the invention
  - the time which has elapsed since the sealing of the patent
  - the measures already taken by the patentee or any licensee to make full use of the invention
  - the ability of the applicant to work the invention to the public advantage
  - capacity of the applicant to undertake the risk in providing the capital and working the invention
  - whether the applicant has made efforts to obtain a license from a patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period (6 months)

Grant and Appeal

- Where the Controller is satisfied that a prima facie case has been made, the Controller will direct the applicant to serve copies of the application on patentee and any other person appearing in the Register of Patents and upon hearing the parties may give his decision
- An appeal lies to the appellate board
- The Controller can terminate the compulsory license when circumstances that gave rise to the grant no longer exist

- Controller shall keep in mind the nature of the invention
- the expenditure incurred in making and developing the invention
- expenditure in obtaining patent and its maintenance
- patented invention is worked and the licensee gets reasonable profit
- patented article is available to public at reasonably affordable price
- license granted is non-exclusive
- the right of the licensee is non assignable
- that the license is for a balance period of the term of the patent or shorter term

Bolar Provision

- **Section 107 A** (a) of the Patents Act:
  - any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information for regulatory approval will not amount to infringement
- This provision is helpful for persons who wish to exploit the patent after the expiry of the terms of the Patent
- as they can obtain the marketing approval before the term of patent expires and can immediately manufacture after the expiry of the term of Patent

Parallel Importation

- Section 107 A (b)
- Parallel Importation of patented products.
- The provision declares that importation of patented products, by any person from a person who is duly authorized under the law to produce and sell or distribute the product, would not be considered as infringement
- The phrase "**duly authorized under the law**" was inserted in place of "**duly authorized by the patentee**" by the Patent (Amendment) Act, 2005
- Effectively, this provision refers to and relies on the applicable local laws of the country exporting the goods to India
- The provision allows export from a country where there is no protection of the article patented in India.
- Parallel Importation provision has been introduced as a mechanism to help in price control through the act of competition
- **Principle of exhaustion of right** is also applicable in this provision

Cross Border Licensing

- Grant of Compulsory License to manufacture and export patented pharmaceutical products to any country having insufficient or no manufacturing capacity by an Indian manufacturer is possible either through the importing country granting compulsory license to the Indian manufacturer or through allowance of importation of the patented pharmaceutical products from India by notification.
- This provision is based on Para 6 of DOHA Declaration on TRIPS Agreement.

Global Perspective on Compulsory Licensing

- This phenomenon of compulsory licensing is a hugely debated issue
- Many developing countries are giving importance to the compulsory licensing because of the unavailability and unaffordability of the medicines, and they are continuously granting more and more compulsory licenses
- The developed countries of Europe, USA are opposing this view as it would make innovation difficult for the pharmaceutical companies

First Case of CL

- India's first case of granting compulsory license was granted by the Patent office in 2012 to an Indian Company called **Natco Pharma for the generic production of Bayer Corporation's Nexavar**
- All the 3 conditions of Sec 84 was fulfilled
  - reasonable requirements of the public were not fulfilled
  - it was not available at an affordable price
  - the patented invention was not worked around in India

- This medicine is used for treating Liver and Kidney Cancer, and one month's worth of dosage costs around Rs 2.8 Lakh
- Natco Pharma offered to sell it around for Rd 9000 making this potentially lifesaving drug easily accessible to all parts of the society and not just the rich people
- The Government took this decision for the general public benefit
- it was heavily criticized by the Pharmaceutical Companies as they felt the license should not have been given
- Natco Pharma is paying the royalties to Bayer at a rate of 6% of all sales on a quarterly basis in accordance with the guidelines set by the **United Nations Development Programme (UNDP)**

- **January 2013**
- Health Ministry of India recommended three anti-cancer drugs
  - Trastuzumab
  - Ixabepilone
  - dasatinib for compulsory licenses
- This will allow the Government to sell these drugs at a significantly lower price and will also allow the people who cannot afford the drugs originally, access to these drugs

Impact of CL

- India, in particular, faces a challenge, owing to the economic condition of the majority population
- On one hand, it has to comply strictly with the **international standards of patent protection** and on the other hand, it has to safeguard **public health**
- compulsory licensing has now become the hope for financially challenged patients in underdeveloped countries
- one of the most controversial topics in International Property matters

Innovation

- In Underdeveloped countries, the innovation of pharmaceutical companies will be less as they will be **dependent on generic drugs**
- They will prefer getting the compulsory license to a generic drug rather than funding the Research & Development separately, which is often a very costly thing
- research-based pharmaceutical companies will not launch patent module in the developing countries as there is always the risk of losing the patent, and losing money in research

Competition and Cost

- Compulsory licensing will increase the number of companies producing generic medicines
- Hence the supply will go up, and the cost will come down
- This will also force the innovator countries to introduce **differential pricing of their patent** module so that they can stand on the market

Patients

- Patients will get medicines at a significantly **cheaper rate**
- big pharmaceutical companies often introduce plans like **free access to medicine** to protect their patents in the developing countries

Patient v. Patent

- The patient versus patent issue is one of the most important problems now in the modern healthcare system
- Although India has only passed one compulsory license yet, the number of compulsory licenses granted worldwide is on the rise.
- The underdeveloped and developing countries want to pass compulsory licenses, and the developed, and the big pharmaceutical companies do not want the compulsory licenses to be passed

Big Pharma

- The main reason the big pharmaceutical companies do not want compulsory licenses to be passed is that it takes a lot of **money and effort to create the drugs**, and even then there is no certainty
- They have to **recoup the costs of the innovation**
- Hence the companies have to fix the cost of their patented module according to the economic status of the country if they want to protect their product from compulsory licensing.