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"Public Health, Medical and Patents"

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Introduction:

Intellectual property is an intangible property created by human mind or intellects either with or without AI intervention. Intellectual property rights are the rights derived due to creation of intellectual property. Such rights are conferred upon the creator who uses such exclusive right to exclude others from using, selling, manufacturing, importing without his/her consent, subject to certain exceptions. This right is provided by government in return for information about the invention either on the product or process.

Patents Act in Act:

Under the Patents and Designs Act, 1911, India had product patents system in case of substances intended to use or capable of being used as food, drug, or medicines or substances produced by chemical process[1]. In 1970, the Government of India introduced a new patents act, namely "the Patens Act, 1970", which excluded the product patent system for pharmaceuticals and agrochemical products and established only the process protection. This change was made to reduce the dependence on imports for bulk drugs and formulations and to develop self-reliant indigenous pharmaceutical industry. As per this 1970 Act, the patent protection (process) was provided for 7 years from the date of application or 5 years from the date of registration, whichever is less.

Non-existence of product patent for pharmaceutical and agrochemical products had a significant impact on the Indian pharmaceutical industry which resulted in activities such as reverse engineering of drugs that are eligible for product patent throughout the world. Due to this, the pharmaceutical industry started producing generic drugs once the international patent expired.

But after India signed the TRIPS agreement, it became a member upon whom the onus was imposed to follow the provisions of TRIPS, as per which the product patent system was implemented.

Evolution of Patent, Medical and Public Health:

Patents play a vital role in the paramedical industry The constitution itself indirectly directs the state to take operative measures in order to enrich the health of the beings under Article

[1] https://www.mondaq.com/india/patent/865888/patents-and-the-indian-pharmaceutical-industry

Volume 1, Issue 2 ISSN 2582-743X

14 and 21[2].As of other countries where products or process are granted with patent protection, the Indian patents act provides patent protection for the product and process. Let's observe the role of patent with the paramedical industry accordance with public health also its evolution.

Kinds of paramedical patent:

Most commonly patents are under two category product and process patent. Product patent is given to the complete manufactured product and process patent is where the process of creating and manufacturing a product. Other few kinds of paramedical patent includes

- Formation patent
- Compound patents
- Technology patents

Formulation Patent

Protection is claim for the composition of the paramedical dosage of the drug. It includes the formulation of particular drug, or class of drugs. This type of patent is taken into consideration for research purposes.

Compound Patent

The chemical structure and component of the drug can be patented. This deals with the composition of chemical matters in the drug.

Technology Patent

Technology includes medical devices used in paramedical industry. Medical devices are patentable in India. Patents Act discuses about medical devices patent, under section 3(i),(f) and (k). Medical devices includes both software and hardware components[3].

WTO and Pharmaceutical patents:

The agreement on Trade Related Aspects of Intellectual Property Rights was negotiated during the Uruguay round trade negotiations of GATT. Pharmaceutical industry was one of the important reasons for incorporating intellectual property issues in GATT. After India signed the TRIPS agreement, it was made to comply with TRIPS provisions which made India to amend its patent law. The amendments were made in a series form, where the first amendment was in form of the Patents Amendment Act, 1999, to give a pipeline protection till country starts providing product patents. Later, Patents Amendment Act, 2002 was made, by which the tenure of patent protection was amended to 20 years for all category of

[2]http://www.legalserviceindia.com/legal/article-3717-patents-and-public-health.html#:~:text=The%20Indian%20Constitution%20also%20indirectly,not%20merely%20to%20import%20inventions

[3]https://www.lexology.com/library/detail.aspx?g=056861c0-14db-4e15-afd4-bacaf7dbd051#:~:text=As%20such%2C%20medical%20devices%20are,best%20avoided%20in%20this%20scenario

Volume 1, Issue 2 ISSN 2582-743X

invention. In the year 2005, third amendment was made via which product patent regime was introduced again in India.

Compulsory licensing:

The patents Act provides for compulsory licensing and licences of right. This is one of the most essential in patent law. It is enforced to prevent the abuse of patent rights which may arise when the patent holder tries to pre-empt entry of competitors using his statutory rights.[4] According to Section- 84, compulsory licensing can be provided only after 3 years has lapsed form the time of grant of patent. Such compulsory licensing shall be issued in the following cases,

- When the patented invention is not available to public at affordable price
- The reasonable requirement of the public not been satisfied with regards to patented invention[5].

In NATCO PHARMA Ltd., INDIA V. BAYER CORPORATION, USA, the then controller of patents issued the order of grant of first compulsory license for patents in India. This patent was related to drug SORAFENIB TOSYLATE sold under the brand name NEXAVAR by Bayer. After getting compulsory licence NACTO manufactured the drug and provided 6% of net sale as 'Royalty' to Bayer at the end of each quarter.

The Patents Act also provided for compulsory licensing for export of patent pharmaceutical products under Section- 92A. as per which, a compulsory license may be issued for manufacture and export of such produce to any country having insufficient or non-existence of manufacturing capacity in the pharmaceutical sector for the concerned product to address the public health problems.

Case study:

- BISWANTH PRASAD RADHEY SHYAM Vs HINDUSTAN METAL INDUSTRIES the bench stated that it is important to make improvement and satisfy the test of invention in order to make the device patentable[6].

Public health with patents

Patent role in medical industry is different from other patents as it deals with the life of the beings. It is important to thoroughly go through the product and its process in order to prohibit any damages in future. The CATO institute referred a decision on a Canadian case which happened on 2002. In the patent case it was said that in the matter of utility of the product it requires two things demonstration and sound prediction of future in the case of a

[4] Injunctive Relief (Chapter 4) - Patent Remedies and Complex Products (cambridge.org)
[5] Intellectual Property Umbrella: Section 90(Terms And Conditions Of Compulsory Licenses) Natco Pharma Ltd. Vs. Bayer Corporation (ipumbrella.blogspot.com)
[6] https://www.lexology.com/library/detail.aspx?g=056861c0-14db-4e15-afd4-bacaf7dbd051#:~:text=As%20such%2C%20medical%20devices%20are,best%20avoided%20in%20this%20scenario

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drug which hasn't been through clinical trial prior to the patent application. This created an opening that the court can intrude in questioning the process of utility post facto or pre decision. This in a way helps to know how it works without any problems in future. Providing patents for medicines also create conflict on pricing the medicine. It is necessary to provide medicines in low cost in developing countries like India. Some option which can be taken into consideration to provide medicine accessible for all citizens are provides as follows[7],

1. It is important to provide compulsory licensing which also includes government use. This is stated under article 31 of TRIPS agreement with a condition of adequate remuneration to the patent holder.
2. The authorities can buy the medicine when it becomes off patents and produce them in market at lower prices.
3. Government can make negotiation with the patent holder for the lower price.
4. Parallel importation can be done with or without the consent of the patent holder.

These are some of the possibilities where the developing nations can bring a better standard in public health.

- BAYER CORPORATION V UNION OF INDIA is a land mark case where the Bayer Corporation applied for patents for the drug 'NACTO' which was used to treat kidney cancer[8]. The corporation claimed for a voluntary patent but it was pushed for compulsory licensing under section 84 of patents act1970. Finally it was granted with non assignable compulsory license[9].

Conclusion:

The role of pharmaceutical industry is very crucial in times like Pandemic. Flexibility in trade regulations exist for emergencies pandemic situations. As like other inventions where patent protection is granted for both product and process, the Indian Patents Act provides patent protection for pharmaceutical products and its manufacturing process.

[7] NATCO Pharma Ltd v. Bayer Corporation and the Compulsory Licensing Regime in Indian – NUJS Law Review
[8] Bayer Corp. v. Union of India (indialaw.in)
[9] https://lawcutor.com/2020/06/26/case-study-bayer-corporation-v-union-of-india1/