A PRESENTATION ON PATENT LAWS IN INDIA AND LANDMARK CASE

INTRODUCTION

A patent is a branch of intellectual property rights like Trademark, Copyright, etc are. The word "patent" is derived from the Latin term "patere" which implies "to lay open," i.e. to make available for public inspection.

A patent is a license that confers an **exclusive right or title to the owner for a limited or specific period of time to exclude others from making, using, or selling an invention and the violation of these exclusive rights or title of the patent holder is known as patent infringement.** In India, the act that govern the patent is Patents Act, 1970.

T**he main motive behind the enactment of the Patent Act is to encourage people to come up with new ideas in their field by awarding them exclusive rights over their inventions.**

CONDITIONS FOR PATENTABILITY IN INDIA

Not each and every invention get patented. A patent is granted to the owners once their invention satisfies the conditions of patentability. **Section 3 and Section 4 of the Patent Act, 1970 provides the list of exceptions that are not considered as inventions and hence are non-patentable.** There are three conditions that need to be satisfied by the inventor to get his invention patent. These are as follows-

The invention should be **novel,** which implies that it should not be in existence.

The invention should be capable of **commercial application.**

The invention should be **non-obvious,** which means that there should be a significant improvement to the previous invention.

PATENT INFRINGEMENT

Patent infringement is the violation of the exclusive rights of the patent holder. As discussed earlier, a Patent is a license conferring an exclusive right or title to the inventor for a set period of time to exclude others from making, using, or selling an invention and the violation of these exclusive rights or title of the patent holder is known as patent infringement. It involves the activities like unauthorized use, production, sale, or offer of sale of the subject matter or Invention of another person‘s patent.

REMEDIES FOR PATENT INFRINGEMENT

Section 108 of the act deals with the reliefs that a court may grant in any suit for infringement include an injunction subject to such terms, if any, as the court thinks fit and, at the choice or option of the plaintiff, either damages or an account of profits. The court may also order that the goods which are found to be infringing and materials and implements, the predominant use of which is in the creation of infringing goods shall be seized, forfeited, or destroyed, as the court deems fit under the circumstances of the case without payment of any compensation.

The basic aim of patent law is the balance of the interests of inventors on one hand and the interests of the public on the other hand. The inventors are rewarded with a limited exclusive right on their invention, for providing technical progress to the public.

Purpose of Patents

Historically, patent protection was designed to encourage innovation and the disclosure of the details of new inventions. Because inventors may be hesitant to publicize their creation lest someone copy it, patent protection provides an incentive to share ideas with a temporary monopoly on their use. The full invention is disclosed in the publicly available application.

LANDMARK JUDGEMENTS

Dr Snehlata C. Gupte v. Union of India & Ors (W.P. (C) No 3516 and 3517 of 2007) Delhi HC) :-

What Shall Be The Actual Date Of Grant Of A Patent?

This case was instrumental in determining when a patent can said to be granted under the Patent Act 1970 (the Act). This lack of clarity led to a scrutiny of the relevant provisions the Act and also the existing process with a time gap between the grant and the issuance of the patent certificate. The Delhi High Court, while holding that the date of grant of a patent is the date on which the Controller passes an order to that effect on the file, noted that the language, “a patent shall be granted as expeditiously as possible” (u/s 43) does point out that a patent has to be granted once it is found that either the application is not refused in a pre-grant opposition or otherwise is not found in contravention of any provision of the Act.

At the core of the legal challenge was the existing process, which resulted in a time gap between the grant of a patent and the issue of the patent certificate. **The court held that the date of the grant of a patent is the date on which the controller passes an order to that effect on the file i.e. on the day in which the Controller makes a decision to grant a patent. The issue of a certificate at a later date is then nothing more than a mere formality.**

The court also came down strongly against the practice of filing serial pre-grant oppositions. through aliases, a practice now fairly common in most pharmaceutical patent cases.

Therefore, the decision taken by the Controller on the file is the determining event for ascertaining the date of grant of patent and the acts of sealing of the patent and entering the same in the Register are ministerial acts evidencing the grant of patent.

Bayer Corporation vs Union Of India :-

India's First Compulsory License

On March 9, 2012, the Indian Patent Office granted its first Compulsory License to Natco Pharma Ltd. for producing generic version of **Bayer Corporations's patented medicine Nexavar (Sorafenib Tosylate), which is used in the treatment of Liver and Kidney cancer.** While the multinational giant was selling the drug at INR 2.80 lakh for a month's course, Natco promised to make available the same at a price of about 3 % (INR 8800) of what was charged by Bayer. Natco was directed to pay 6 percent of the net sales of the drug as royalty to Bayer. Among other important terms and condition of the non assignable, non exclusive license were directions to Natco to manufacture the patented drug only at their own manufacturing facility, selling the drug only within the Indian Territory and supplying the patented drug to at least 600 needy and deserving patients per year free of cost.

Aggrieved by the Controller's decision, Bayer immediately moved to the Intellectual Property Appellate Board (IPAB) for stay on the orderalleging that the grant of compulsory license was illegal and unsustainable. The Board rejected Bayer's appeal holding that if stay was granted, it would definitely jeopardize the interest of the public who need the drug at the later stage of the disease. **It further held that the right of access to affordable medicine was as much a matter of right to dignity of the patients and to grant stay at this juncture would really affect them.**

Bayer then filed an appeal challenging the compulsory licence granted to Natco by the Controller-General. The Board stated that **the invention must be available to the public at a reasonably affordable price and if not, compulsory licence can be issued** and observed that the Sub-sections (a), (b) and (c) of Section 84(1) are separated by the disjunctive 'or' and therefore, even if one conditionis satisfied, the Controller will be well within his rights to order compulsory licence.

The Board further noted that The R&D costs and the prices of other drugs do not assist in deciding what the public can afford reasonably. It stated that the reasonably affordable price necessarilyhas to be fixed from the view point of the public and the word 'afford' itself indicates whether the public can afford to buy the drug.

It also stated that even if it takes the appellant's own number (i.e. the number of affected patients) it finds that the supply made by it cannot be said to be adequate and the price definitely is the factor that will determine whether the public will reach out for a particularinvention.

The Board held that the Controller was right in holding that the sales of the drug by the appellant at the price of about 280,000/- wasalone relevant for the determination of public requirement and he was also right in considering the purchasing capacity of the public and the evidence available to conclude that the invention was not reasonably affordable to the public.

On the percentage of royalty that was to be paid by the Respondent to the Appellant (6% that was fixed by the Controller), IPAB increased it by 1 percent but did not change any other terms and conditions of the licence.

The IPAB dismissed the appeal and confirmed the grant of Compulsory license stating that it has dealt with each of the issue indetail in view of the significance of the order of compulsory licence made in India for the first time.

N0VARTIS AG VERSUS UNION OF INDIA

CITATION: (2013) 6 SCC 1

COURT: Supreme Court of India.

BENCH: Aftab Alam, J.; Ranjana Prakash Desai, J.

FACTS

One of the predominant pharmaceutical companies, Novartis International (The Appellant) filed an application for patent registration of a drug called '**Glivec'**. This drug was invented using the **Beta Crystalline form of "Imatinib mesylate"** used to treat cancer.

Initially, the application in India was not considered because Section 5 of the Patents Act, 1970 restricted the grant of a patent for products. After the 2005 amendment, which included patents for products along with processes, the application for patenting Glivec was taken into consideration.

The application by the appellant, when first filed, was rejected by the Madras Patent Office as well as the IPAB, on the grounds that the drug in question is a known substance and does not induce any 'enhanced efficacy' than the previous drug 'Zimmermann' patented in the US. Thus, it cannot be considered to include an inventive step under Section 3(d) of the Act. The IPAB's reasoning for the rejection involved the prevention of 'evergreening' of an already patented product which would eventually cause an obstacle in the provision of affordable medicines .

Thus, a SLP was filed by the appellants in the Supreme Court of India under Article 136.

ISSUES

Whether the **‘inventive step’** requirement under section 2(1)(j) is fulfilled by the appellant?

Whether **Section 3(d)** of the Act bars the registration of the appellant’s patent?

LAW

Section 2(1)(j), Indian Patents Act, 1970 – Defines Invention as a new product or process which includes an **inventive step and is capable of industrial application.**

Section 2(1)(ja), Indian Patents Act, 1970 – Defines **Inventive step to mean a non-obvious feature which involves a technical advancement when compared to a previous product.**

Section 3(d), Indian Patents Act, 1970 – **New form of a known substance which does not result in an enhanced efficacy is not patentable.**

Section 83, Indian Patents Act, 1970- The general principles applicable to the working of patented inventions.

ANALYSIS

The Appellant primarily argued that the Zimmerman patents registered in the US differ from Glivec in terms of the form of the substance used. The appellant's product is in a beta crystalline form which satisfies the novelty requirement because the Zimmerman does not constitute the beta crystalline form of imatinib mesylate. It was contended that since the Zimmerman patent contains no mention of a crystalline structure or teach a person how to prepare a particular polymorph of the salt, the process of production of the salt and the synthesis of the relevant crystalline form would possess the characters to pass the Novelty test.

When the court analysed this contention, **it concluded that since the substance in question was already a known substance, it does not qualify the test of invention as under section 2(1)(j).**

Secondly, the appellant had stated that their product in the beta crystalline form has an enhanced efficacy over the imatinib mesylate used in the previously registered drug, thus it satisfies the test of selection under Section 3(d).

The Respondents denied these arguments and stated that imatinib mesylate in beta crystalline form is not original or non-obvious as there are pre-existing publications about the component in addition to the disclosures in the Zimmerman registration application. **Further, in order to prove the novelty of the same, it was contended that 'efficacy' in Section 3(d) should be considered as a therapeutic efficacy and not merely physical efficacy.**

The court accepted this argument and rejected the appeal filed by **Novartis by stating that although the beta crystalline is a new form of a known substance (Imatinib Mesylate),the efficacy of the substance is already well known.**

CONCLUSION

This is one of the Landmark judgments of the Supreme Court which ensured affordable access to medicines for all while defining the scope of the Patents (Amendment) Act, 2005. **The Court, in effect, emphasised that while considering the efficacy in case of any drugs or medicine, the efficacy under section 3(d) always refers to 'Therapeutic efficacy' as contented**. Further, it stated that the intention of the amendment provisions to the Patents Act, 1970 also includes **ensuring that patented products do not get 'evergreen' protection.** The Indian patent office does not take a liberal approach towards the grant of patent protection for pharmaceutical products to ensure prevention of unaffordability of life saving drugs. Section 3(d) by barring all incremental inventions achieves this objective. The Hon'ble Court in its judgement, clearly stated that since India is a developing country, **the availability of medicines at affordable rates is a necessity.**

THANK YOU