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Protecting Innovations: The Role of Patents in the Pharmaceutical Industry

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ABSTRACT

Intellectual property rights (IPR) have become crucial for conserving innovation, facilitating R&D, and ensuring fair competition in the rapidly evolving field of medicine. This paper aims to place particular emphasis on the role of patents in the protection of the pharmaceutical industry. Since it stimulates innovation, investment, and creativity along with offering incentives to produce innovative medications and therapies, patent protection is a prerequisite for the perpetual growth of the pharmaceutical sector. This paper aims to study how patents, on the one hand, guarantee and regulate access to reliable and effective medicines, and the other hand foster creativity and innovation. The study also aims at how patents can be an integral tool to promote Research and development in the Pharmaceutical Industry, which in turn can be used for providing patients with quality drugs and a committed medical system along the continual evolution of the healthcare industry. It also aims at how this protection is of significance for the producers in the pharmaceutical industry, in terms of monetary and non-monetary benefits.

I. INTRODUCTION

Intellectual Property is born out of the knowledge/intellect of a person, who is known as the creator/inventor of such property. Intellectual Property Rights (IPR) are the exclusive rights bestowed upon these creators for their unique and creative inventions and novel efforts. The patent is one such recognition given to an intellectual property that recognizes and exclusively protects the creative and novel efforts of an inventor and is a monopoly right conferred upon the inventor to exploit his inventions for a fixed duration. This duration allows the inventor to commercialize and monetize his/her inventions and reap back the investments made in research and development. This statutory right and protection are governed by The Patents Act,1970. The role of the pharmaceutical industry, which is one of the most dynamic industries, is indispensable in the current world, with several discoveries and advancements being made in the field of medicine every day to safeguard millions of lives. The continuous and rapid emergence of new diseases necessitates evolution, growth and changes in the pharmaceutical

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industry, which requires the pharmaceutical industry to patent such inventions to exercise exclusive monopoly rights over them. Research and Development, popularly known as R&D, is one of the areas of prime importance in all fields of study, and the pharmaceutical industry is not an exception to it. As we all know, the R&D process in an industry is of key importance as it is this part of the industry that helps evolve new products and steers the industry towards progression in the desired field. However, the investments required for R&D are exorbitant, and since the inventor invests such a huge sum, it is but natural that the creator needs and expects to reap the economic benefits once an invention is out in the market. Particularly in this industry, there is a huge risk involved at the developing stage itself, and it requires a well-structured R&D set-up and scientific knowledge to avoid huge losses, owing to the giant investments made. Patents encourage the pharmaceutical industry to invest in R&D through the grant of such exclusive rights, which are then monetized by these inventors for their novel ideas and painstaking efforts. A patent can be obtained for the invented product or the process of invention.

On the other side, the pharmaceutical industry is relied upon by millions of commoners, and hence, it is necessary to ensure that the grant of monopoly rights to the creator does not result in the invention becoming unaffordable/inaccessible to these people. The monetization of pharmaceutical inventions should not defeat the basic purpose for which the invention is developed. The quality and utility of the invention are completely tested and scrutinized before granting a patent and letting it out in the market for consumer use, through which the grant of a patent indirectly contributes to consumer protection as well.

II. IMPORTANCE OF PATENTS IN THE PHARMACEUTICAL INDUSTRY

India, which is the world's biggest provider of generic medicines provides for more than half of the world's demand for vaccination apart from supplying 40% of the US's generic drugs and 25% of the UK's pharmaceuticals. Patenting of such medicines and drugs helps protect the exclusive rights of the inventor in the pharmaceutical industry, thereby restricting others from inventing similar products and processes. The purpose of patenting is two-fold, one being the protection of the invention and the other one being the commercialization or monetization of the invention. As mentioned earlier, the investment risk in this field is humongous, which makes it indispensable to secure the investment made in terms of money and time to develop such inventions, which further necessitates the requirement of protecting these inventions through patents. A drug is shielded by a patent when it has been conceived or developed and is protected using novel ways, and such protection also covers the manufacturing process. A patent is also

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far safer and highly preferred in India due to the absence of trade-secret laws. Thus, the protection of inventions through patents is the sole defence for pharma products as far as the Indian pharmaceutical industry is concerned. A robust patent framework defends breakthroughs in the process of invention from conception/formulation of novel ideas to commercialization of the desired resultant product. The development and administration of inventions require concrete financial management for research and development endeavours. A patent is one of the IPRs that can be conceived as a discrete commodity capable of being transacted through licensing, collaborations, and various other means, which can be monetized to stabilize financial requirements for further investments in R&D and to generate revenue.

PATENTS

Intellectual property is particularly significant in the pharma industry since it remains a crucial factor for the perpetual creation of unique remedies for newly emerging diseases. To protect a distinctive product or healthcare application through patenting, an individual or entity must either file an application for patent protection or keep confidential information. Not all drugs are patentable inventions since some of them fall under the category of non-patentable inventions. Several requirements require being satisfied for an applicant to be eligible for the grant of a patent. The core necessities for obtaining a patent for an invention include the invention being innovative, non-obvious and new, involving an inventive step and capable of industrious application. When juxtaposed with similar formerly patented concepts, a non-obvious creation does not give the same type of support or provide the same type of information as the earlier one. This test is one of the most significant ones to be taken into account while analyzing the novelty of an innovation. It also contributes to assessing contemporary similar ideas. The creation also ought to be distinctive and non-preexisting. Pre-existing creations encompass any priorly registered inventions, whether they are completely identical or remarkably similar. It is additionally vital to remember that even if such an invention is employed, it is still difficult to obtain a patent if the opposition can prove pre-existence. Also, where an inventor ought to have sheltered his/her invention under patents, intending to get complete protection rights over it, but he has failed to do so, there is still a potential possibility of acquiring patent protection if a patent application with an identical conception is filed subsequently and remains unregistered as on the date of submission of application by the former. Finally, the innovation must be useful, implying that it is bound to fulfil a definite objective. A patent provides substantially stronger security since, unlike trade secrets, a drug/medicinal formula cannot be reconstructed, which might culminate in the breakthrough idea being exploited or copied. Hence, the patenting of inventions empowers pharmaceutical

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manufacturers to reap tremendous economic benefits by providing innovative drugs/therapies along with exclusive monopoly rights obtained through patents. This is in line with the fact that the innovator is the only legitimate proprietor of the invention's commercial entitlements, with full authority to sell or license it.

III. EVERGREENING OF PATENT IN THE PHARMACEUTICAL INDUSTRY

The most successful approach for prolonging the useful lifespan of patents and boosting revenue for inventors is commonly referred to as "evergreening." Securing numerous patents by making minor changes and developments to the independent aspects of a single product is a strategy termed "patent evergreening". **Section 3(d) of Chapter II of the Indian Patent Act, 1970** deals with those inventions that are not patentable; which reads “the mere discovery of a new form of a known substance or 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.”, and aims at preventing ever-greening and protecting genuine inventors. It is a popular argument that evergreening has the greatest impact in the healthcare field, although an equal possibility of it being employed in any other sector also exists. A company may preserve its creation from adversaries for an extended period owing to the filing of supplementary patents that are linked to the primary patent. Incorporating additional applications that are linked to the initial patent constitutes the mechanism by which evergreening operates. Consequently, patent holders can prolong the lifespan of their improvements and guard them against adversaries for additional time, through the mask of a distinctive enhancement of the already existing product. For additional protection of the invention, the procedure generally includes filing multiple subsequent patents that are developed upon the primary patent. Deterring competitors from tapping into patent gaps to create an identical good or service without infringing on the original patent is usually the primary objective in cases of the evergreening of patents. Following the payment of annual fees, patents are granted in India for a time frame of 20 years. An invention becomes a part of the public domain immediately following the expiry of the patent period, implying that every business, organization, or individual may produce, market, or import it. This is precisely something that occasionally makes pharmaceutical companies attempt to retain their exclusive ownership of the invention even after the patent's term has run its course. To ensure that no other business protrudes in this domain to manufacture or market the product/idea, a new patent application for minor changes to the initial concept. To prevent the evergreening of patents, provisions have been inserted in the **Indian Patents (Amendment) Act, 2005**, with **Section 2(1)(l)** dealing with absolute novelty and **Section 2(1)(ja)** emphasizing on presence of inventive

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step and non-obviousness. **Section 3(d)(3)** also denies protection to pharmaceutical advancements unless there is a significant enhancement in the final product, thus curbing applications for trivial changes and removing ambiguity as to the patentability of products.

IV. THE NOVARTIS CASE IN EVERGREENING OF PATENTS

Novartis, a Switzerland-based Pharmaceutical Company, applied for a patent for a cancer drug, a beta-crystalline form of imatinib mesylate (Glivec), on July 17, 1998, in Chennai. The company also filed a suit against Indian companies engaged in this field even before it received a patent for the same and was also successful in receiving an interim order for exclusive marketing rights in India. After the amendment in 2005, the application was scrutinized and six oppositions were filed in the process, one being withdrawn, **u/s 25(1) of the Indian Patents Act,2005**. The examination by the Controller resulted in the denial of a patent for the said product on the grounds of the improvement being trivial and known already, which led to Novartis filing a writ application for the same before The Madras High Court. This judgement is of significance due to two reasons. Firstly, it clarified that the amended Section 3(d) of the Act gave absolute discretion to the Controller to decide the patentability of an invention, in line with which a test has been laid down by the section itself to verify if there is a genuine enhancement in the efficacy of the product as claimed. Secondly, it clarified the meaning of efficacy and held the word to be at par with therapeutic and functional efficacy. Thus, through this judgement, the Court impeded the misuse of "Evergreening of Patents" and it has proved to be a landmark judgement in this field from then on.

V. CHALLENGES IN PROTECTION THROUGH PATENTS IN THE PHARMACEUTICAL INDUSTRY

Managing creative risks while trying to obtain a competitive edge over competing organizations is one of the major problems in the field of pharmaceuticals. Pharmaceutical R&D carries a high chance of failure when developing new treatments that do not fulfil strict safety criteria and are eventually discontinued often, even though it has taken years of investment. After a drug initially gets developed, it takes several years for the drug to overcome developmental impediments. Drug industries are hence obligated to shift the emphasis of their R&D efforts from developing innovative techniques to generate common drugs to developing revolutionary pharmaceutical molecules and novel drugs when product patents eventually constitute the mainstay of safeguarding intellectual property. This comes along with enhanced paper requirements. The period of protection of a drug is now shorter when compared to the duration of approval, which is prolonged. There are also challenges faced by the Indian pharmaceutical

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Industry after the amendment of the country's patent law to comply with the TRIPS Agreement which includes restrictions on generic companies in manufacturing generic medicines and drugs, increased patent terms, the need for policy adjustments which mainly include balancing of interests of patent holders and manufacturers of generic medicines and drugs, and difficulties in patent enforcement once a patent is obtained.

VI. CONCLUSION

In recent times, many indigenous companies have resorted to reverse engineering techniques to create some of the modern inventions, which results in financial losses. There is a growing need for an effective strategy to optimize the returns through new inventions on one hand while ensuring patent protection on the other. Genuine innovation has always been the key to ensuring patent protection and shall continue to remain so. Promoting such innovation through investments shall be one of the prime factors for the overall growth and economic advancement of the company and industry. The right kind of strategy to invent new products and implement the chosen strategy at the proper platform for achieving the desired results requires proper strategic planning at periodic intervals. However, when this is rightly done, then the R&D in the pharmaceutical industry becomes easily affordable by the inventors while giving simultaneous benefits to the public as well, who are the ultimate beneficiaries of the inventions and innovations.

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