

Compulsory License: A boon for the patients or a challenge for the Innovator companies- Case study?

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Abstract

The provision of compulsory license as per the Indian Patent Act, 1970 provides a provision for a generic company to manufacture, market and sell the already patented drug without the approval from the innovator company. The compulsory licenses are granted on the basis of various factors like affordability and access ability of the drug, if the invention is nor workable in India or in national emergency cases so that the concerns of the innovator company in terms of recovery of the funds used to innovate the drug as well as of the population affected from life threatening disease in terms of affordability and accessibility. The present manuscript discusses the cases of compulsory license filed by different pharmaceutical companies from time to time and the future of the compulsory license in India.

Key words: *Compulsory license, Sorafinib, Dasatinib, saxagliptin, Indian Patent Office*

Introduction

Patent is an intellectual property which gives the innovator company the legal rights to manufacture, use, market and sell the invention exclusively without the intervention of others for a limited period of time [1-2]. This makes sense in the way that the innovators companies spend million dollars on creating an invention which is novel, non obvious and commercially viable. Therefore exclusive rights are given to Innovator Company for limited period of time so that it can recover the expenses incurred during the development of the invention. Drafting of patent is an art which determines the boundary of the rights in the form of claims [3]. Normally the innovator company enjoys that exclusive rights of 20 years from the date of application of patent application and this term can vary from one country to another [4]. History has witnessed many cases where the patent applications in the pharmaceutical companies are designed in such a way that leads to the extended rights to the innovator company. This is also called ever greening of

patent by which the innovator company can enjoy the market share for extended period of time which bring substantial monetary benefit [5]. For example,

Merck and Co., filed a patent application, US6699871 in 2002 for sitagliptin as a product which is used to treat type II diabetes which is going to be expired in 2022. It filed another patent application US7326708 for phosphate salt of sitagliptin which is the active form of the drug and the patent for the phosphate salt is going to be expired in 2026. That means, even though the patent for the active pharmaceutical ingredient is going to expire in 2022 but no other Pharma companies can enter the market as phosphate salt, which has better therapeutic activity is going to be expired in 2026. This gives the innovator, extend benefit of the market share for next 4 years. As the innovator company holding the patent has to recover the cost incurred for the development of the drug in a limited period of time, therefore the cost of the drug is higher than the generic version. There are certain life threatening drugs [6-10] where the cost of the therapies is too high to be afforded by the patients. Developing countries and under developed countries are the worst effected due to this. In order to cater the needs of poor, there is provision for compulsory licensing in India under Indian Patent Act, 1970 and at international level according to TRIPS agreement [11]. It is a provision given by the government of a specific country to third party to make, use and sell the product which is covered by patent law without taking the permission from the patent holder. Compulsory license is normally granted in case where the patented invention is not available at affordable price, reasonable requirements of the population have not been met with respect to intention, in case where the invention is not worked in Indian territory, in case of national emergency etc. It has become the most happening section of Indian Patent Act 1970.

Natco Vs Bayer Corp's case for Nexavar

Natco has been the first pharmaceutical company in India to be granted compulsory license to manufacture and sell the blockbuster drug Nexavar (Sorafenib) to treat liver and kidney cancer in 2012. The innovator company Bayer Corp's has product patent US7235576 which is expiring in 2020. It filed a plea against the generic manufacturer Natco in Supreme court of India against the decision of high court to revoke the compulsory license. The court asked Bayer Corp's to produce the expenses incurred for the development of the product in front of the controller. It was found that the innovator company Bayer Corp's was able to recover that expense in the first

year of the grant of the patent. Moreover, the therapy cost was approximate Rs. 2.8 lakh per month as compared to Rs. 8880 for the Natco generic version. In addition, Bayer Corp's was not able to convince the court that it can provide the drug in sufficient and sustainable quantity in India. Therefore the court ruled down the Bayer Corp's plea to revoke the compulsory license and it approached the Intellectual Property Appellate Board against the decision which stated that the stay on the decision would be against the need of the patients who need this life threatening treatment but cannot afford it. This was the first landmark decision for compulsory license for all the generic companies in the developing where the patient's well being and access to the treatment was given preference over the million dollars profit of the innovator companies on the basis of affordability in case of life threatening drug [12].

Lee Pharma ltd. Vs Astrazenica for Saxagliptin

In 2015, Lee Pharma Ltd. Filed an application for the compulsory license for the anti diabetic drug Saxagliptin to treat type-II diabetes in the Indian Patent Office. The drug was protected by Astrazenica for the patent application US6414126 which is expiring on 2020. The decision of the controller was in favor of the innovator company on three grounds. Lee Pharma Ltd. applied for the compulsory license to Astrazenica more than 13 months prior to the filing of application in Indian Patent Office which against the time frame of 6 months. In addition, Lee Pharma Ltd. was unable to prove that the current therapy was un assessable to the patients as there are many other substituents which were present in the market with same therapeutic category at the same cost. Also, the price difference between the generic version of saxagliptin and the innovator drug was not substantial. Therefore the concern for the affordability of the drug was not justified. Finally, Lee Pharma was unable to prove that the invention was not worked in the territory of India and therefore the controller of Indian Patent Office turn down the request for compulsory license to Lee Pharma Ltd [11].

BDR pharmaceuticals Vs Bristol Mayer Squib Co. for Sprycel

Sprycel (Dasatinib) has been proven to be chemotherapeutic option for the treatment of chronic myeloid leukemia. It has been protected by patent application US7125875 till 2020 by innovator company Bristol Mayer Squib Co. The patent application was filed in 2006. BDR pharmaceutical had requested for the compulsory license to Bristol Mayer Squib Co. in 2012.

BDR claimed that Sprycel sold by Bristol Mayer Squib Co. cost approximately Rs. 165680 per month to the patient whereas it will make the drug available at a cost of Rs. 8100 per month. BDR pharmaceutical also added that it will make the drug available at free of cost to certain percentage of patients as per doctor recommendation. IN response BDR pharmaceutical raised certain points regarding the consistent supply of the drug, quality issue, safety and environmental issues etc. BDR pharmaceutical did not respond to the issues raised by Bristol Mayer Squib Co. as it took the queries as rejection and made an application for compulsory license in 2013. The controller turned down the plea of BDR pharmaceuticals on many grounds. As per the controller, BDR pharmaceutical did not make an effort to obtain compulsory license from the innovator as it did not respond to queries raised. The applicant claim that the attorney of innovator company made comments publically on behalf of innovator company that their strategy for asking queries was to avoid outright rejection but the controller rejected the plea that the statement of the attorney could not be taken as an evidence against innovator company and patentee can ask for the additional information to ensure the credibility of the applicant. Also the controller asked the reason for delay in application from BDR pharmaceutical of almost 1 year after getting queries from patentee. Finally the court conclude that BDR pharmaceutical did not refrained itself from interacting with the patentee for the grant of voluntary license for the purpose of getting compulsory license and rejected the request made by BDR pharmaceutical [13].

Conclusion

India has a good capability to manufacture the generic drugs. These landmark cases for the compulsory license can pave a way for the generic companies in India to apply for the compulsory license. The decision in the case of Natco Vs Bayer Corp's can be seen as step of Indian government and Indian Patent Office to stop the monopoly of the big multinational innovator Pharma companies so that the drugs are available as affordable price to end users. On the other hand, some are of the thoughts that this decision would discourage the Pharma companies to invest on the research and development of new drugs. While the decision in the cases of Lee Pharma ltd. Vs Astrazenica and BDR pharmaceuticals Vs Bristol Mayer Squib Co. are encouraging for the innovator companies as their interests have been taken care by the Indian patent office. Future might witness more rivalry between innovator and the generic company as

lot of money is involved. The outcome of the future cases will give clarity about the future of compulsory license in India.

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