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A Case Study of India

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Findings of the Study

The Indian Patent Act, 1970 provides certain exclusive rights to the patentee which enables him to exclude others from using the patented invention while the patent protection subsists. However, these rights granted to the patentee are not absolute, there are various obligations and marketing regulations which are imposed on the patentee while patentee resort to the commercial exploitation of the patents. Once the patent is granted, patentee is required to work the patent in the public interest. Failure to work the patent may result in revocation or issuance of compulsory license. Furthermore, while resorting to the commercial exploitation of the patent rights, patentee is not at liberty to accrue economic incentive from his patented invention at his own terms and conditions. Here again he is required to adhere to certain limitations which are imposed on him by the patent law. The provision such as *section 140* which deals with the avoidance of the restrictive conditions vehemently declares that incorporations of certain conditions will render the patent agreement as void.

Furthermore, patent rights are further subjected to Competition law restraint, while exercising his exclusive rights if patentee goes beyond the limit of monopoly, such conduct will come under the scrutiny of the Competition Commission of India (CCI). There have been many instances where CCI has strictly implemented provisions of competition law while regulating the patent rights. The conduct of the patentee is scrutinized in such a manner that interest of the general public is given ample considerations. On the other hand, in the United States and European Union some degree of licensing freedom is provided to the patentee which is mostly not seen in Indian patent system

In addition to this there are certain exceptions provided under the *Patent Act 1970* which tend to regulate the exclusivity enjoyed by the patentee concerning his invention. In other words there are certain instances where patented invention may be put to use without obtaining any

authorizations from the patentee. However, the ambit of these exceptions is much wider in India as compared to other jurisdictions such as USA or UK. These exceptions include compulsory license where State as well as Controller is given ample power to deal with the patented invention. In addition to this we have bolar provision which act is an exception to the exclusive rights enjoyed by the patentee. It provides concession for the generic manufacturer to deal with the patented invention for the research purpose and generate information and other important details which is used by the generic to seek approval from the regulatory authorities for generic version of the innovator product. This provision is of great utility specially for a country which have great potential for producing generics and biosimilars such as India. However, this provision does seem unfair especially for innovator and original drug manufacturer who invest huge sum of money in the development of new drug. Which is then easily imitated by the generics in order to launch their own version in the market the moment patent expires.

Furthermore, exclusive rights of the patentee which includes act of making, selling, using, offering for sale or importing for those purposes the patented product or process is further subjected to the provision which is contained in *section 107A(b)*. This *section* deals with the concept of parallel importation and doctrine of exhaustion. According to this section importation of patented product is allowed by any person from any person who is authorized under law to sell or distribute such product and will not amount of infringement. This provision directly hits the exclusive right to import enjoyed by the patentee and also attempts to divert from the protection afforded by the *TRIPS Agreement*.

Therefore, it is concluded that undoubtedly patentee is given exclusive rights, but at the same times these rights are heavily regulated. but it is important to understand that patents are special rights and in order to govern them there is a need to devise clear and unambiguous rules which demarcate boundaries between patent and regulatory authorities. This will provide opportunity to the patentee to freely exercise his rights and promote innovation and further development. Although providing absolute rights to the patent holder will never be conducive for the healthy functioning of the market and consumer freedom. However, rights provided to the patentee must provide him reasonable avenue and reasonable amount of freedom to secure returns on his investment. This is possible only when ambiguities in the law is redressed and areas are identified which requires deliberation by the law makers.