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ISSUES OF PATENT LAW IN THE PHARMACEUTICAL INDUSTRY: AN ANALYSIS OF COMPULSORY LICENSING AND THE NEED FOR GENERIC MEDICINES IN INDIA

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Abstract

This research paper analyses how patent as exclusive right works in the pharmaceutical industry and explains why it is important to maintain a balance between parent right and the right to life. Innovators manufacture life saving drugs and generate profit but there are many people who desperately need these drugs but can't afford or can't easily access such drugs. In the duration of patent, the innovators get an opportunity to recover their costs invested in R&D and generate profit but after the expiry of this period it is expected from them to release their exclusive rights and let the other manufacturers create an affordable alternative of that costly medicine. This paper explains how the innovators want to maintain monopoly and how they create barriers in the development of affordable drugs. It shows that accessing life saving drugs is easier for rich patients which necessitates intervention of the government to ensure the availability of affordable life saving drugs to all. There is a mechanism of compulsory licensing as well to make the life saving drugs widely available in certain situations. This paper also analyses the concept of compulsory licensing and explains the measures to make the affordable generic medicines widely available in India. Doctrinal method of research has been followed in this research work. Various previous research works, Indian Patents Act and relevant judgments have been analysed to completely understand the issues and to generate helpful suggestions.

Keywords*: Patent Law, Patent Evergreening, Compulsory Licensing, Pharmaceutical Industry, Public Health, TRIPS Agreement.*

1- Introduction

Innovation is a significant part of the pharmaceutical industry to develop life-saving drugs, which demands proper patent protection as well.[1] In cases related to access to drugs, affordable medicines, ethical considerations, market dynamics, etc., the pharmaceutical industry faces a lot of challenges related to exclusive rights and patents. The solution of this problem demands incentivization of research and development (R&D) along with the adequate protection of intellectual property rights of the innovators.[2] Strict enjoyment of patent rights in the pharmaceutical industry can prevent the access to essential medications, hence a balance has to be created. In this balance, the innovators should be rewarded as well as the public access to essential medications should also not be restricted.

By investing their precious time in the expensive R&D works, the innovators take huge risks for which they must be rewarded. This exclusion right in the form of Patents are typically granted for 20 years from the filing date.[3] This duration creates a balance and innovators are rewarded with the exclusive right for 20 years. Granting this form exclusive right and reward influence the innovators to remain involved in new & future R&D works as well. As said above, innovation is a significant part of the pharmaceutical industry to develop life-saving drugs but the pharmaceutical industry faces a lot of challenges related to exclusive rights. They constantly face pressure to relax their exclusive rights and make the life saving drugs more accessible which has potential to cause monetary loss to the innovators as well.

High drug prices have always been an issue especially in developing countries. High drug prices and lack of access to life saving drugs has created a huge debate on the right to health versus proprietary rights. In cases related to access to life saving drugs, affordable medicines, ethical considerations, market dynamics, etc., the pharmaceutical industry should be encouraged to create a balance between the right to health versus proprietary rights. The solution of this problem demands incentivization of research and development (R&D) works along with the adequate protection of intellectual property rights of the innovators. The TRIPS[4] Agreement of the WTO[5] aims to create a balance through compulsory licensing but still various kinds of pressure and legal hurdles are faced by the pharmaceutical industry.[6]

2- Monopoly or unwillingness to relax the exclusive rights

The purpose of innovating the essential drugs is to save lives but there are some practices in the pharmaceutical industry related to ***Patent Evergreening*** which strengthen the exclusive rights of the innovators but make the drugs costly and less accessible. This is a controversial practice in which the aim involves to have the exclusive rights for the lifetime period. This practice of establishing monopoly is often done by securing new patents on minor modifications, new formulations, delivery methods, or by transforming the uses of an existing drug.

These tactics prevent the access to affordable drugs but the intention behind doing modification or transformation is always not done with the purpose of maintaining the monopoly. To bring genuine improvements, the need for modification or transformation becomes necessary, that is why the innovators can not be completely blamed here. In this way, creating a balanced right to health versus proprietary rights in the pharmaceutical industry is a complex issue. For the purpose of safeguarding the interests of common people, maximum competition should be encouraged in the pharmaceutical industry with innovation of affordable drugs. Relaxations in the exclusive rights will allow the competitors to create an alternative of the costly medicines. In this way, the practice of patent evergreening should be discouraged. Applications for modification, transformation, etc. should be allowed only in genuine, non-obvious innovations.

Just like the practice of patent evergreening, there is a practice of ***"patent clustering"*** *or* ***"patent thickets"*** which is also used as a tool to prevent competition and maintain the monopoly. These practices in the pharmaceutical industry help the innovators to strongly maintain their exclusive rights but common people suffer from the issue of high prices especially in the emergency cases where accessibility of live saving during become much needed. ***"Patent clustering"*** or ***"patent thickets"*** is a tactic which is used as a tool to prevent competitors from entering into the market of affordable medicines. By applying this tactic, companies file numerous patents around a single drug which creates a dense web of intellectual

[1] Bryan Mercurio & Daria Kim (eds.), *Contemporary Issues in Pharmaceutical Patent Law: Setting the Framework and Exploring Policy Options*, Routledge, London, 2021.
[2] Prathiba M. Singh, *Patent Law (In 2 Volumes)*, 1st ed., Eastern Book Company, Lucknow, 2019.
[3] Prathiba M. Singh, *Patent Law (In 2 Volumes)*, 1st ed., Eastern Book Company, Lucknow, 2019.
[4] Trade-Related Aspects of Intellectual Property Rights.
[5] World Trade Organization.
[6] Srividhya Ragavan, *Patents and Trade Disparities in Developing Countries*, Oxford University Press, New Delhi, 2012.

property rights related to that single drug. Existence of such complex patent related practices discourages the competitors from entering the market. Due to such practices, the challenges related to IPR still exist and due to the costly affairs it becomes quite difficult to launch affordable medicines.

The innovators want to maintain monopoly or they normally possess unwillingness to relax the exclusive rights because their life saving drugs provide huge revenue for them and when the period of patent expires their revenue suddenly falls sharply which is known as ***"Patent Cliff".*** In the duration of patent, the innovators get an opportunity to recover their costs invested in R&D and generate profit but after the expiry of this period it is expected from them to release their exclusive rights and let the other manufacturers create an affordable alternative of that costly medicine.

Production of affordable drugs requires the first innovators to release their rights over their drugs and when such rights are released, the generic manufacturers get a chance to create affordable alternatives of that life saving drug. But, as said above, innovators don't want to lose the profits, so they use different tactics to maintain their monopoly. In this way, the government has to interfere by establishing a strict measure to balance the proprietary rights. with the right to health.

3- Compulsory Licensing and Public Health

Incentivization of R&D works along with the adequate protection of intellectual property rights of the innovators is a great solution to create a balance between proprietary rights with the right to health. The TRIPS Agreement of the WTO aims to create a balance through compulsory licensing but still various kinds of pressure and legal hurdles are faced by the pharmaceutical industry.[7] TRIPS allows compulsory licensing to permit a government to authorize a 3rd party to produce a patented product. This permission may also include the use of a patented process without the patent consent of the patent holders.[8] In cases related to access to drugs, affordable medicines, ethical considerations, market dynamics, emergency etc., the pharmaceutical industry is expected to relax its exclusive rights and patents. The aim behind compulsory licensing is to create a balance between the right to health versus proprietary rights. The government aims to incentivize research and development along with the adequate protection of intellectual property rights of the innovators but with assurance of easy availability of life saving drugs. Strict enjoyment of patent rights in the pharmaceutical industry can prevent the access to essential medications, hence a balance has to be created. In this balance, the innovators should be rewarded as well as the public access to essential medications should also not be restricted.[9]

Regulatory Exclusivity and Data Protection: Generic manufacturers successfully bring the alternative of the costly drugs by understanding the composition of the drugs, past clinical trials, etc. But if such data is not shared by the previous innovators then a huge challenge is created for generic manufacturers. Apart from the patent rights, in the field of protection of IPRs, the pharmaceutical innovators also get to enjoy regulatory exclusivity. This right grants a period of market protection to their drugs based on the data submitted for regulatory approval. Generic manufacturers face a barrier due to this data exclusivity from relying on the clinical trial data of the innovators to gain their own marketing approval for a set period.

4- An Analysis of Emerging Jurisprudence Regarding Compulsory Licensing

Compulsory licensing permits a government to authorize a 3rd party to produce a patented product.[10] This permission may also include the use of a patented process without the patent consent of the patent holders. In cases related to access to drugs, affordable medicines, ethical considerations, market dynamics, emergency etc., the pharmaceutical industry is expected to relax its exclusive rights and patents. The aim behind compulsory licensing is to create a balance between the right to health versus proprietary rights. The government aims to incentivize research and development along with the adequate protection of intellectual property rights of the innovators but with assurance of easy availability of life saving drugs. Strict enjoyment of patent rights in the pharmaceutical industry can prevent the access to essential medications, hence a balance has to be created. In this balance, the innovators should be rewarded as well as the public access to essential medications should also not be restricted.[11]

Flexible patent policies in a country are prime requirements to enforce compulsory licensing.

[7] Srividhya Ragavan, *Patents and Trade Disparities in Developing Countries*, Oxford University Press, New Delhi, 2012.

[8] Tanusree Debnath, *Compulsory Licensing of Pharmaceutical Patents and Access to Medicine*, Satyam Law International, New Delhi, 2017.

[9] Feroz Ali Khader, *The Law of Patents: With a Special Focus on Pharmaceuticals in India*, LexisNexis, Gurgaon, 2011.

[10] Adarsh Ramanujan, *Patent Law: An Comprehensive & Analytical Commentary*, Wolters Kluwer India Pvt. Ltd., New Delhi, 2015.

[11] Van Anh Le, *Compulsory Patent Licensing and Access to Medicines: A Silver Bullet Approach to Public Health?*, Palgrave Macmillan, Cham, 2021.

Regarding these flexible patent policies, India initially allowed only process patents, earning it the title "pharmacy of the world." Product patents were introduced in 2005 with India's compliance to the TRIPS, but safeguards like compulsory licensing under **Sections 84 & 92**[12] were retained.[13] In India, applications for compulsory licensing can be filed under **Sections 84** after three years of a patent. The grounds can be high prices, the drug not meeting public requirements or not being worked in India. Compulsory licensing is also allowed under **Section 92** in cases of urgency, national emergency, or public non-commercial use. In this process applicants are required to show failed attempts at voluntary licensing. Permission for compulsory licensing also depends upon the evaluation of the Controller regarding public interest, high prices, affordability & the capacity of applicants to supply. In a developing country like India, accessibility of affordable drugs are quite necessary,[14] which has made the availability of generic medicines a fundamental requirement. High cost of the drugs, lack of availability, etc. are the prime reasons in India to bring the concept of affordable generic medicines. The landmark case of ***Bayer Corporation vs Natco Pharma (2013)***[15] marked a significant progress in making generic medicines available in India because it was the first case in which a compulsory licence was granted.[16]

5- Implications and Challenges

Availability of affordable medicine depends on the existence of multiple drug manufacturers. For the purpose of safeguarding the interests of common people, maximum competition should be encouraged in the pharmaceutical industry with innovation of affordable drugs. Alternative routes for R&D have to be created. The need to transfer profits for R&D purposes forces the innovators to maintain their monopoly on their drugs. The government should also invest in domestic R&D and it should increase manufacturing capacity to make affordable medicines widely available. Incentives to innovator companies should also be given to encourage them to release their exclusive rights over life saving drugs. The tactic of patent evergreening must be controlled. Applications for modification, transformation, etc. should be allowed only in genuine, non-obvious innovations.

The legal hurdles and barriers must also be eliminated. Conditions for granting compulsory licensing must be made more clarified and simplified to reduce legal and political hurdles.

The concept of voluntary licensing and the conditions for it have to be properly enumerated. Many times applications have been rejected due to unavailability or unfulfillment of the conditions of voluntary licensing. What is the "reasonably affordable price" must be properly explained to make more applications eligible for compulsory licensing.

Fostering dialogue through international cooperation is also a needed step. To develop equitable solutions, it demands continuous collaboration among nations, pharmaceutical companies & civil society organizations.[17] To make the medical cure affordable in India, there is also a need to extend compulsory licensing to essential diagnostics and medical devices. IPRs are not absolute rights. Clear guidelines should be released to explain the situations in which public demands can be given priority over IPRs.[18]

6- Conclusion & Suggestions

Innovation is a significant part of the pharmaceutical industry to develop life-saving drugs, which demands proper patent protection as well. In cases related to access to drugs, affordable medicines, ethical considerations, market dynamics, etc., the pharmaceutical industry faces a lot of challenges related to exclusive rights and patents. The solution of this problem demands incentivization of research and development (R&D) along with the adequate protection of intellectual property rights of the innovators. Strict enjoyment of patent rights in the pharmaceutical industry can prevent the access to essential medications, hence a balance has to be created. In this balance, the innovators should be rewarded as well as the public access to essential medications should also not be restricted. By investing their precious time in the expensive R&D works, the innovators take huge risks for which they must be rewarded. This exclusion right in the form of Patents are typically granted for 20 years from the filing date. This duration creates a balance and innovators are rewarded with the exclusive right for 20 years. Granting this form exclusive right and reward influence the innovators to remain involved in new &

[12] The Patents Act, 1970 (Act 39 of 1970), ss 84 & 92.
[13] K.M. Gopakumar, "Compulsory Licensing in India: Status and Prospects," in Carlos M. Correa (ed.), *Research Handbook on Intellectual Property and Access to Medicines*, Edward Elgar, Cheltenham, 2020, pp. 241–262.
[14] Tanusree Debnath, *Compulsory Licensing of Pharmaceutical Patents and Access to Medicine*, Satyam Law International, New Delhi, 2017.
[15] 2014 (60) PTC 277 (Bom HC).
[16] Sudhir Kumar & A. Yerram Raju (eds.), *Compulsory Licensing: Patent Law & Policy Lessons from India*, NALSAR University of Law, Hyderabad, 2022.
[17] Srividhya Ragavan, *Patents and Trade Disparities in Developing Countries*, Oxford University Press, New Delhi, 2012.
[18] Michael S. Mireles, *Compulsory Licensing for Emerging Economies: Pharmaceutics, Innovation and the Law*, Cambridge University Press, Cambridge, 2018.

future R&D works as well. As said above, innovation is a significant part of the pharmaceutical industry to develop life-saving drugs but the pharmaceutical industry faces a lot of challenges related to exclusive rights. They constantly face pressure to relax their exclusive rights and make the life saving drugs more accessible which has potential to cause monetary loss to the innovators as well. The innovators want to maintain monopoly or they normally possess unwillingness to relax the exclusive rights because their life saving drugs provide huge revenue for them and when the period of patent expires their revenue suddenly falls sharply which is known as "Patent Cliff". In the duration of patent, the innovators get an opportunity to recover their costs invested in R&D and generate profit but after the expiry of this period it is expected from them to release their exclusive rights and let the other manufacturers create an affordable alternative of that costly medicine.

Production of affordable drugs requires the first innovators to release their rights over their drugs and when such rights are released, the generic manufacturers get a chance to create affordable alternatives of that life saving drug. But, as said above, innovators don't want to lose the profits, so they use different tactics to maintain their monopoly. In this way, the government has to interfere by establishing a strict measure to balance the proprietary rights. with the right to health. To make the affordable medicines widely available in India, here are given some helpful suggestions:

1. For the purpose of safeguarding the interests of common people, maximum competition should be encouraged in the pharmaceutical industry with innovation of affordable drugs.
2. Alternative routes for R&D have to be created. The need to transfer profits for R&D purposes forces the innovators to maintain their monopoly on their drugs.
3. The government should also invest in domestic R&D and it should increase manufacturing capacity to make affordable medicines widely available.
4. Incentives to innovator companies should also be given to encourage them to release their exclusive rights over life saving drugs.
5. The tactic of patent evergreening must be controlled. Applications for modification, transformation, etc. should be allowed only in genuine, non-obvious innovations.
6. Conditions for granting compulsory licensing must be made more clarified and simplified to reduce legal and political hurdles.
7. The concept of voluntary licensing and the conditions for it have to be properly enumerated. Many times applications have been rejected due to unavailability or unfulfillment of the conditions of voluntary licensing.
8. What is the “reasonably affordable price” must be properly explained to make more applications eligible for compulsory licensing.
9. Fostering dialogue through international cooperation is also a needed step. To develop equitable solutions, it demands continuous collaboration among nations, pharmaceutical companies & civil society organizations.
10. To make the medical cure affordable in India, there is also a need to extend compulsory licensing to essential diagnostics and medical devices.

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