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PHARMACEUTICAL COMPULSORY LICENSING IN EMERGING MARKETS: IS IT A WELFARE LICENSING OR THREAT?

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ABSTRACT

India, which has 2/3rd patent protection to foreign MNC pharma companies and 24% contribution of generic industry to economy, took a big step of Compulsory Licensing of life saving drugs to Indian Generic Pharma company, Natco Pharma ,against the MNC patentee Bayor Corporation. Decision lands up as a boon for the Indian as well as global patients who depend upon Indian Generic Industry for affordable drugs. India took its first compulsory license in 2012 as till 2005, Indian Patent Act does not have the provision of Pharmaceutical and health related Product Patent. The decision also came up with the future prospective for generic companies to take the initiative in the R & D as well as drug development for their own. Also, compulsory licensing burdens the foreign patentees to commercialize the patented drug in Indian market and manufacture it in the Indian Territory, which leads to a healthy competition in pharma industry. This paper extensively studies the overview and post CL implications in the various spectrum of innovation, fair competition ,countries economy ,price control, research trend, Licensing trend of pharmaceutical sector vis a vis Foreign counterparts.

KEY WORDS: Compulsory Licensing, generic pharma industry, Indian Patent Act, Reverse Engineering, Patented drugs, fair competition

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1-INTRODUCTION

India, which has 2/3rd patent protection to foreign MNC Pharma companies and 24% contribution of generic industry to economy is the third largest, in terms of volume and thirteen largest in terms of volume, with a total production output of $23.24 billion with 17% per year growth rate, where 52 % of generic drugs were exported to developing countries for the need of the patients.[1] In Natco- Bayor CL case as well, the drug was not even manufactured in India and hence has high prices which is evident to be the cost of R&D expenditure and drug development and launch in market but studies have shown that Compulsory license has negligible effect on innovation cost depending upon the future demand and modification of the drug and the market significance of the drug and the cost can be well compensate by the royalties as well as fair competition with the compulsory licensee and further drug improvement. In 2005, after WTO TRIPS and Patent Act Amendment in section 5, there is a monopoly of patentees which are generally MNCs due to which domestic patients are left out from the reach of the patented drug due to non availability or non affordability of the drug. Hence, the generic companies can produce the drug by the modification in method of production, easily by reverse engineering.

2. COMPULSORY LICENSING

Compulsory licensing is the non exclusive, non assignable and non transferable license, issued by the patent office, after 3 years of patent grant on the ground of non availability; non affordability and non working in Indian territory, to any interested company who has already give an attempt for license to patentee. U/S 84, at any time after the expiration of 3 years from the date of grant of a patent, any interested person can make an application on the grounds of non availability, non affordability and non working of the patent in Indian Territory.

2.1 India's First Compulsory licensing: A Case Study

India's first compulsory license for life saving patented drug Nexavar, useful in the treatment of advanced stage liver and kidney cancers, granted by Bayor corporation has been given to the Indian generic Pharmaceutical company, Natco pharma ltd., on the grounds of non availability, non affordability and non working of patent in Indian territory. The grounds were based on the grounds that patntess is neglecting the needs of patients and non availability of drug as well as non affordable prices (2,80,000 INR per month), and non working in India as it has been only imported from other countries.[2] The compulsory license which was non exclusive and non assignable, was issued at the terms of 6% royalty to patentee and distinct from patented drug by the understanding that only 2% patients were benefitted by drug and highly unaffordable even after excluding Drug innovation price.[3]

3.PROSPECTIVE OF COMPULSORY LICENSING

CL does have various perspective ensured, including its impact on economy, innovation, competition, market and the pharmaceutical drug development strategies.

3.1 CL in Developed vs Developing Countries

It has been stated in WTO report as well that CL has been mostly being explored in Developed countries as compared to the developing countries. Taking an example, Malaysia is more rely on the drug importation from Indian generic companies in spite of compulsory licensing and well tweeted India has one grant CL till now and the case is same for all the rest countries. The reason being that the Developed countries are more into the innovation and the patent strategy of developed countries including US, Europe etc, emphasizes the concept of ever greening by the incremental patenting.[7].Table -1 gives the number of CL given in countries after 1977.

Table1
Number of CL given in countries after 1977

S No.	Country	Number of CL
1	Canada	613
2	US	1500
3	UK	100
4	Germany	12
5	Israel	1
6	Australia	0
7	South Africa	0
8	India	1

3.2 CL impact on Innovation

It has been quoted controversially that the forceful permit of assessing the patent by the means of CL would led to the decrease in the interest of the patent holder in the innovation and R&D [6]. But the research being conducted and the papers reported evaluates that the companies which has faced the CL or companies which are supposed to face, aremore efficiently orkiwork on the innovation by their R&D so that to compete with their companions and also working more on the innovation for the recovery. It has been stated that the research has been more toward HIV Profitable drugs as shown in figure 1.

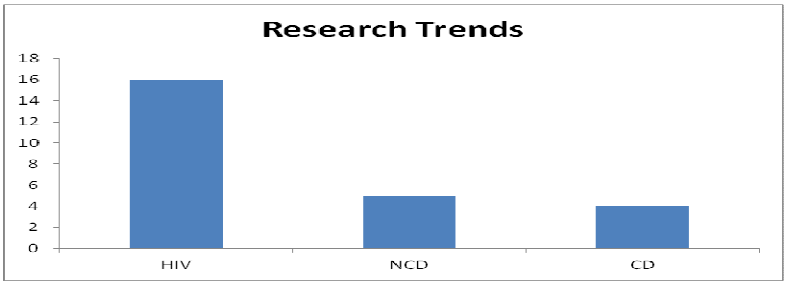

Figure 1
Impact of CL on research of diseases(NCD : Non Common Diseases, CD: Common Diseases)

3.3 CL on Competition

CL ensures a fair competition to the companies for the sake of consumers where IP protection provides monopoly to the patentee, the CL ensures a fair competition between patent holders and generic companies with the benefit of the patients in the form of price control and availability.

3.4 CL and Economy

CL should not have any impact on the country's economy as well as on the patent holder company. As CL has been granted when the patented drug was neither available nor being produced in the market [10]. Hence there are low market or consumers and after the CL, the patentee enjoys the royalty which can be substituted as the income forms that small market of the country.

3.5 CL and Price control

WIPO has stated that CL can contribute as a tool as well as a framework for the price control of the patented drug in developing countries where the innovation skills are negligible[8]. It is further stated that the with the CL, domestic companies came into force which automatically reduces the cost as the product has manufactured locally if the quality of the drug should be kept same. There are various ways by which these trends of Licensing affect the price has been shown in figure 2.[5]

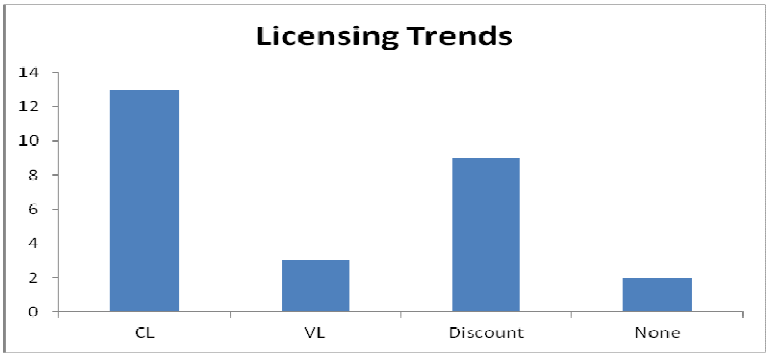

Figure2
Various trends of licensing on patent (CL: Compulsory License, VL: Voluntary Licensing)

3.6 CL and Pharmaceutical trend

It has been observed that most of the CL has been given to life threaten diseases and in that too mostly to the AIDS drug and after the introduction of CL, the middle income drug areis more emphasized for the innovation as depicted in Figure 3 and the pharmaceutical drug innovation has been more shifted towards the more profitable drugs for high revenues.[9]

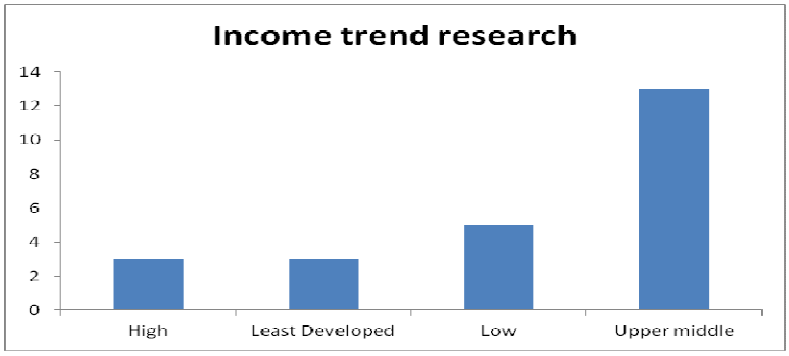

Figure 3
Impact of CL on different income pharmaceuticals

Decision lands up as a boon for the Indian as well as global patients who depend upon Indian Generic Industry for affordable drugs. India took its first compulsory license in 2012 as till 2005, Indian Patent Act does not have the provision of Pharmaceutical and health related Product Patent. Hence, the generic companies can produce the drugs which were patented in other countries by the modification in method of production, easily by reverse engineering and easily marketed in India[4]. In 2005, after WTO TRIPS and Patent Act Amendment in section 5 and inclusion of pharmaceutical product patents, there is a monopoly of patentees which are generally MNCs due to which domestic patients are left out from the reach of the patented drug due to non availability or non affordability of the drug [12]. In Natco- Bayor CL case as well, the drug was not even manufactured in India and hence has high prices which is evident to be the cost of R&D expenditure and drug development and launch in market but studies have shown that Compulsory license has negligible effect on innovation cost depending upon the future demand and modification of the drug and the market significance of the drug and the cost can be well compensate by the royalties as well as fair competition with the compulsory licensee and further drug improvement. [6] The case can be understood as the conflict between innovation and necessity where the price of innovation can be stated on the basis of the R&D expenditure, its orphan drug belongingsnes and safeguards, clinical trials and commercialization of the drug as well as the maintain ace cost of the patent, which

can be thus be conflicted with the necessity of the drug to patients to whom the drug should be available in an ethical manner. The 2005 post regime has surrounded the interest of various MNC companies to IP protect their innovated drug in India as well. This flooded the highly priced, non commercial drugs in Indian patent records but non commercial in Indian markets as Indian generic pharmaceutical companies were excluded from the grant [13]. The necessity makes the compulsory license available in the Indian patent system.

4. IMPACTS OF THE COMPULSORY LICENSE

Grant of pharmaceutical compulsory license in India firstly shows a disagreement and non belief of Multinational Pharmaceuticals in the provision as they consider it to be a threat on the exclusive rights which patent grant provided them and the economy which they expect from the drug throughout the drug development process. The grant also reflects a generous vision towards the need of the drug by the patients considering need is the first priority and the patent should be available and affordable to the patients for whom the drug was innovated. It also stated that Indian IP system has a strict vision as the second compulsory application was being rejected on the grounds that no efforts for license grant was taken by the applicant to the patentee so the IPO compulsory licensing decision was neither a matter for any any person CL nor it's a matter for evergreening[11].

5. FUTURE PROSPECTS

The decision also came up with the future prospective for generic companies to take the initiative in the R & D as well as drug development for their own. Also, compulsory licensing burdens the foreign patentees to commercialize the patented drug in Indian market and manufacture it in the Indian Territory, which leads to a healthy competition in pharma industry .Secondly, in cases of epidemics and life threatening situations market availability of a drug is solely humanitarian and it should be implemented as such. Whatever the loss incurred by the company might be, it cannot be worse than the loss of lives due to unaffordability of the lifesaving drugs. Maybe it is the time to turn around and protect the people for whom the drugs are actually manufactured rather than the profits incurred.

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