Abstract

Compulsory licensing allows countries to produce patented foreign innovations without the consent of the foreign patent holders. Compulsory licenses came into force since the developing countries couldn't afford the cost of technology to produce medicines and high price incurred due to the discovery, which could not be afforded by the masses. On the other hand, authorization to produce the drug other than the patent holder comes at the cost of numerous factors like low remuneration to the patent holder, decreased innovation etc. The review paper therefore, outlines how the compulsory license effects the motivation of innovation by the pharmaceutical companies and proposes solutions as to how the compulsory license can be implemented in an effective possible way.

Keywords: Compulsory license, Innovation, patents, non-working

1. Introduction

Compulsory licensing, the practice of authorizing a third party to make, use, or sell a patented invention without the patentee’s consent can be traced back to the 19th century when Europe proposed to have compulsory license as the means of exploitation of patents and to avoid it being termed as “non-working” under patents act of 1883, under section-22 [1, 2]. Subsequently, the Paris convention recognized this and stipulated compulsory license in its Hague 1925 revision. It was argued that the development of a new drug is a time-consuming and expensive process. The overall cost from discovery to market can be heterogeneous for different therapeutic areas. Additionally, reconfiguration of research and development process to develop superior versions of existing molecules further adds on to the overall R & D expenditure. Thus, to combat the rising costs and stimulate investment in drug development, the creators of new drugs can apply for intellectual property rights (a patent) protection of their intangible creations. An exclusive right provided by a patent protects the investments made by companies during drug development by preventing other companies from making the new drug for a fixed period of time and by providing incentives to the creators of new drugs in the form of payments and royalties from other companies for the use of their creation.

However, the extent and enforcement of intellectual property rights that govern the international protection of goods and services have been variable across the globe. Then, in 1995, the World Trade Organization (WTO) was born. By providing a set of ground rules for trade among nations at global or near-global level, the WTO aimed to ensure progressive liberalization of trade through negotiations between the trading partners. International agreement of Trade related aspects of Intellectual Property rights (TRIPS), administered by the World Trade Organization (WTO) laid down minimum standards for many forms of intellectual property (IP) regulation as applied to nationals of other WTO Members [3, 4]. However, IP protection in the form of for drugs (pharmaceuticals) meant that many drugs would be too costly for use in developing countries [5]. Thus, while maintaining incentives for the creator the TRIPS Agreement allows governments to license the technology to the third party. Such a statutory license was termed as a “compulsory license.”

Box: Case study on Compulsory license:

In 2007 Thailand issued compulsory licensing on Abbot’s Kaletra and produced a generic version of Kaletra. Kaletra, which is also known as Aluvia in some countries, is an important second-line AIDS medicine, and the ritonavir component is also widely used as a stand-alone protease booster that can be combined with other unpatented protease inhibitors. Prior to compulsory licensing, Thailand was not able to afford Kaletra for Thailand’s HIV patients, who received treatment through the country’s universal healthcare system. A generic version was sold at a price half of Kaletra’s. In 2007, Thailand estimated that the cheaper generic version increased the number of HIV patients who received treatment by 400%.
2. The Indian law on compulsory licensing

The Patents Act, 1970, as amended in 2005, dedicates Chapter XVI to the, Working of Patents, Compulsory Licenses and Revocation [6]. The Act clarifies that the limit of Compulsory Licensing covers patented products as well as patented processes. The Indian Patent Act gives a pointer to the objects of compulsory licensing and requires that while granting a compulsory license, the general conditions in the section have to be focused on the working of patents. The Indian law provides for the grant of a compulsory license under Section 84, aiming to prevent the abuse of a patent as a monopoly and to make way for commercial exploitation of invention by an interested person [6]. Under this section, any person can make an application for grant of compulsory license for a patent after a period of three years, from the date of grant of that patent. The grounds that may be vouched to apply for the same include: (i) The reasonable requirements of the public with respect to the patented invention have not been satisfied; (ii) The patented invention is not available to the public at a reasonably affordable price. (ii) The patented invention is not worked in the territory of India. Section 89 too specifies and clarifies the general purposes of grant of the compulsory license as elucidated under Section 84. The purposes include: (i) the patented inventions are worked on a commercial scale in the territory of India without any undue delay and to the fullest extent that is reasonably practicable; and (ii) The interests of any person for the time being working or developing an invention in the territory of India under the protection of a patent are not unfairly prejudiced [6].

Also, Section 84 (6) specifies that the Controller shall take into account the following factors while considering the application for Compulsory License: (i) The nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patent or licensee to make full use of the invention; (ii) The ability of the applicant to work the invention to the public advantage; (iii) The capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted; and whether the applicant has made genuine efforts to obtain a license from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit [6].

Section 90 of the Act also empowers the controllers to settle the terms and conditions for compulsory licenses, which include financial concerns such as royalty and remuneration to the patentees. Section 92A, puts forth the provision for export of pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector and in certain exceptional, to address public health issues. Such country has to either grant compulsory license for importation to the manufacturer of the pharmaceutical product or issue a notification for importation into that country. However, in the circumstances of National Emergency or Extreme urgency or public non-commercial use including public health crises, relating to Acquired Immuno Deficiency Syndrome, Human Immuno deficiency virus, tuberculosis, malaria or other epidemics, to avoid any delay, the compulsory license will be granted, immediately under section 92 (3) under the terms and conditions that the articles manufactured under the patent shall be available to the public at the lowest prices [6].

2.1 Controversies surrounding the compulsory license

Grant of Compulsory license holds major challenges. On one had compulsory licenses ensure the affordability by masses in developing countries but long-term benefits from issuing compulsory license may be a distant dream. It stems from the fact that licenses should strike a proper balance between the government (authorizer), compulsory licensee (government, firm’s private public), and IP owner (unwilling licensor). The debate currently revolves around 3 issues

1. Is it fair to give 1% royalty or royalty free to the owner?
2. Could the local supply be guaranteed not to create grey market?
3. Would the grant dishearten owners against further innovative activity, and/or hurt the motivation of innovation leaders?

These controversies led us to review the effects of compulsory license on innovation.

2.2 Innovation a main driver of growth

Innovation has been a key factor promoting growth and new opportunities. The creation, dissemination and application of innovative knowledge have been one of the greatest challenges so far in terms of sustained growth. Business organizations have now realized that innovation is an important strategic tool to stay ahead in the competition. Thus, overall a generic model on how to innovate must be functionally in place as a part of the company policy.

2.3 Factors affecting Innovation

Patents give the creator a right of property for their innovation, grant monetary rewards, and address various public goods problems via technological development. However, patent has its own disadvantages and compulsory licenses are therefore, generally authorized in the event of undesirable behavior by the patentee, such as anti-competitive, non-working, or blocking behavior; in the event of national emergency in return of a small compensation to the patent holder [7]. Compulsory license in a long term could hamper innovation. The impact of a license on the licensor’s innovation depends on a variety of factors and possible solutions to maintain the company’s motivation in innovation:

- The price at which a compulsory license is set will determine whether and how much innovation is affected. If a compulsory license price point depends essentially at what a patentee is demanding, there is no absolute reason to
anticipate that innovation will be eventually harmed by not reaching the hands of public. On the other hand, if the price point is set at a level far below the market price then it could effectively strip the patentee of its monopoly profits.

- As to market significance, compulsory licenses can vary in degree as to the competitive threat they pose to licensors. If a compulsory license covers a known product in a licensor’s target market, the licensor and the licensee will have to share the same market. Under the above definition, the market significance of this license is high because the licensor’s market is directly threatened. Conversely, if the license covers a market that is unimportant to the licensor, or it covers a product that has yet to be proven or for which the market is immature or untested, there is a good chance that the licensee and licensor will not compete head to head. The significance of such a license may be rather low.

- Whether a license is predictable is also an important characteristic. Unpredictable licenses that cover only existing technologies are more limited in scope than those that are predictable and cover future inventions.

Although the unanticipated loss of exclusivity that accompanies an unpredictable compulsory license may influence a company’s decisions about investing in follow-on innovation, development, and commercialization.

2.4 Compulsory license: No Impact on Innovation

Studies have shown that compulsory licenses actually have had a good impact on companies to innovate more. A study of 70 firms subject to compulsory license showed a significant increase in R&D expenditure in comparison to the firms under no influence of compulsory licensing [8]. This was explained through the fact that the firms were under intense pressure to innovate so that they are ahead of their competitors.

2.5 Compulsory license: not an effective measure for affordability

Compulsory license is granted with the sole aim that developing countries have access to newer drugs at an affordable price. However, some experts from biotechnology industrial organization (BIO) do not believe that the compulsory licensing of innovative products or technology generally is an effective means of promoting access or affordability of healthcare [9]. Furthermore, in a country like India where the ROIs are uncertain, issuance of compulsory licences leads to demotion of incentives for the innovator.

Thus, blatant use of compulsory licenses could jeopardize India’s goal of developing a research oriented biotechnology industry, and is an unsound policy. It is also important to note that compulsory licences not just impact Big Pharma but SMEs as well. Thus, jeopardizing the entire ecosystem supporting innovation in biotechnology including government and private sector investment funding.

3. Case study analysis on Compulsory licenses and its Impact on Innovation: Eli Lilly vs. FTC

In 1980, the FTC charged Eli Lilly with involvement in a wide-ranging conspiracy, dating back to 1952, with other manufacturers of pancreatic insulin. The FTC ordered the firm to license the know-how and rights relating to both its existing and future insulin-related patents. Any potential entrant who, within five years of the decree, stated a bona fide intention to produce and sell insulin products in the United States would obtain access to Lilly’s intangible assets, including all patents issued and applied for during the five-year period. Significantly, Lilly could impose a charge on the licensee equal to the amounts actually spent by Lilly in acquiring, or financing the research and Development. No information is available on whether any companies came forward and took advantage of the compulsory license made available by the consent decree. However, Lilly continued to dominate the emerging human insulin market in both research and development, surpassing major milestones during the five-year period covered by the consent decree. In 1980, following the initial production of human insulin through recombinant DNA techniques in 1978, Lilly initiated clinical trials in the United States of its human insulin product “Humalin” and invested in research facilities to carry out additional work. In 1982, the FDA rewarded Lilly for its efforts with the first approval for human insulin in the United States [10].

The broad order, covering future patents issued on any insulin technology and allowing a potentially large number of licensees, effectively prevented Lilly from obtaining patent protection over its insulin technology during the affected period. Faced with this severe version of compulsory licensing, the company was potentially discouraged from any innovation in insulin technology during the five-year period. Additionally, Lilly probably at least delayed patent applications until after the licensing period, relying instead on trade secret or other forms of protection. The one significant mitigating factor, however, was the license’s provision that the licensee could be asked to contribute to the R&D expenses.

Based on a few indicators, Lilly continued to aggressively pursue insulin R&D during the period covered by the license. For example, patenting behaviour did not appear to be affected. The company filed for seven patents over the five-year licensing period, whereas fewer than seven patents were filed during the periods five years prior and subsequent to the licensing event combined. Several factors seemed to motivate Lilly’s continued innovation during the licensing period, one is historical market leadership and another factor was that Lilly was an early leader in the research leading to the production of human insulin through recombinant DNA methods in 1978. Through subsequent testing and commercialization, the company was often first or second to introduce products of increasing purity to market. Likewise; insulin was always one of Lilly’s most important products. Shortly after the company took its first license in
1923, insulin accounted for half of all Lilly’s profits, and in 1994, it was still the company’s second largest revenue producer. Insulin continues to be a high revenue generator, despite being viewed as a commodity product due to significant barriers to entry such as the high cost of clinical trials for new biotechnology products and the cost of an efficient manufacturing facility. Finally, Lilly continues to face continuous pressure from competitor Novo Nordisk; in 1980 the two companies together held nearly 80% of the insulin market (53% by Eli Lilly and 24% by Novo Nordisk), and by 1995, the two virtually split 91% of the market (Eli Lilly capturing 46% and Novo 45% of the market). The pressures generated by market leadership, a desire for market dominance, and competition provided significant motivations for Lilly to continue to innovate, even during the compulsory licensing period.

4. Conclusion: Proposing Solutions
To resolve this conflict of interest the only possible solution proposed by intellectual property (IP) experts is that the nations should have an intention to harmonize and integrate IP policies with the rest of the world. This means that both the WIPO and WTO should play crucial role in conflict resolutions. The granting of compulsory license should require detailed clarification, particularly regarding the conditions underlying it. It should take into account the patent holder’s sentiments with adequate remuneration and the economic value of the patent should be taken into account. Furthermore, licenses in case of national emergency should be granted only for specific duration of time. These solutions might help implementing compulsory license in most effective way; unless the same is translated in the national legislations by adopting a simplified and harmonized guideline.

References:

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