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# COMPULSORY LICENSING AND BAYER PROVISION: THE ROOTS OF IMPLICATION OF TRIPS

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## INTRODUCTION

Patent is one of the instruments which are mostly debated for its role under pharmaceutical industry. What is patent all about? Why is it in debate nowadays?

The simple answer to all these questions is that Patent is an instrument by which grant of some privilege, property or authority is made by the government or the Sovereign of the country to one or more individuals. The debate started when India signed General agreement for trade and tariff in 1994 wherein it agreed to implement all the flexibilities of TRIPS within a given time period. India faced challenges while adopting the provisions of TRIPS as maintaining stability between the provisions of TRIPS (Trade Related Intellectual Property Rights) and Protection of Public Interest was the aim of Indian policy makers.

TRIPS brought in drastic change in the existing patent law wherein it introduced Product patent, Rights of Patentee. The provisions also extended the term of patent. Certain modifications/ flexibilities were also introduced by TRIPS agreement, which were: Compulsory licensing, Bolar exemption and Parallel imports.

Introduction of product patent led to a great loss for the generic pharmaceutical industry in India as they were no longer allowed to continue the process of "reverse engineering". On one hand the implementation of TRIPS restricted the pharmaceutical industry in terms of producing generic drugs; on the other hand it opened up opportunities for the industry in terms of investments in Research and Development of molecules. [1]

[1] Impact of Patents on Indian Pharma Industry's Growth and Competency: A viewpoint of Pharmaceutical Companies in India
By: Manthan D Janodia, J Venkata Rao, Sureshwar Pandey, D Sreedhar

Compulsory Licensing was incorporated by Section 84 of Indian Patent Act, 1970. Also, there was recognition of India's Bolar Exemption under section 107A of Indian Patent Act, 1970. No doubt every new implication has its own positive and negative effect what needs to be observed is which of the effect is more prevalent and what is the general view of pharmaceutical companies on such changes. Most of the companies viewed the change within the patent system as positive and accepted and started gearing up for the same where others found it to be an opportunity for basic Research and Development.

## PATENT AND PHARMACEUTICAL INDUSTRY.

- **Implication of TRIPS**

As mentioned in the introduction part that India being a member to TRIPS was asked to implement certain provisions of this agreement. India was given a transitional period to implement the changes required. One of the biggest changes incorporated within the Patents Act, 1970 was recognizing product patent. Initially, when only process patent was granted the concept of Reverse engineering was practiced at large by the generic pharmaceutical industry which allowed expensive drugs available in the foreign market to be reproduced cheaply and made available to Indian public. This practice was restricted through the incorporation of Product Patent wherein a manufacture was given patent on his product giving him a monopoly over that product.

Another addition into the patent law was recognizing compulsory licensing under section 84 of Indian Patent Act, 1970. Section 84 states that at any time after the expiry of 3 years from the date of grant of patent, any interested party may make an application for grant of Compulsory License on patent on the following grounds:

- ✓ That the reasonable requirements of public with respect to patented invention have not been satisfied.
- ✓ That the patented invention is not available to public at reasonably affordable price.
- ✓ That the patented invention is not worked in the territory of India.[2]

Revised on: 11 August 2009

[2] Page No: 38 Law Relating to Intellectual Property, Dr B.L Wadhera, 5th Edition

This means that compulsory license helps making the medicine available in the country at reasonable prices.

Further, Section 107A of Indian Patent Act, 1970 acts like a defense for the patent infringement, when the invention so patented is either sold or used by a third party for the purpose of research and development. The main intention of this section is to ensure the marketing of generic products into the market which are already manufactured.

- **Impact of Implications on Pharma Industry.**

With introduction of product patent in the Patents Act, 1999 a huge reduction in continuation of process of reverse engineering which was practiced earlier by the generic manufacturers was observed. Such reduction created a Monopoly in hands of Patent Holders and gave them opportunity to sell the product at high prices. This led to high charging of prices for life saving medicines which were not being supplied to poor people suffering from illness. To overcome this problem concept of compulsory license and Bolar provision was recognized.

Before heading towards the concept of compulsory license let us see into the effect of Implications of Trips on Research and Development. With the introduction of product patent more and more firms in India were encouraged to undertake more research for inventing more drugs rather than continuing drugs made by developed nations. Also, some big Indian players are likely to spend more on research and development; this will lead to development of new drugs. Companies like Dr Reddy's and Ranbaxy have already started investing in research and development, smaller firms who relied upon reverse engineering are now tensed as they have limited capital and technology to invent new drugs that can be patented and exploited by them.

In order to protect their Rights, Para 6 of Doha declaration instructs council for TRIPS to find solution to problems faced with insufficient or no adequate pharma production capacity in making effective use of Compulsory License.

- **Compulsory License: Flexibility of TRIPS.**

The idea of protecting pharmaceuticals, especially essential drugs, has always been a debating topic. One side is the pharmaceutical giants who are supported by developed world and who claim that granting of compulsory license will reduce investment in Research and development.

Critics pointed out that these days drug companies focus upon developing the most saleable product and not the most needed one. They state that longer patents will only enhance their profit and will not lead to research and development of new and needed drug. On the other side, are the developing nations who want to shorter the patent life and want flexibility to grant compulsory license in order to make medicines available for people at affordable prices.[3]

One of the most important cases related to compulsory license is Natco Pharma vs. Bayer Corporation. The decision of this case led to a major change in the patent industry wherein to maintain public health compulsory license was granted to a generic manufacturer.

The case mainly involved the issue of granting compulsory license to Natco Pharma on the grounds that Bayer Corporation was not fulfilling the conditions and thus according to section 84 of Indian patent act, Natco is entitle for compulsory licensing.

The brief facts of this case are Bayer Corporation was manufacturing a cancer drug for liver/ kidney named Nexavar which was patented in India. Natco Pharma first applied for a voluntary license to Bayer Corporation which was rejected by them in 2011. Further, Natco approached the controller for grant of compulsory license. This was granted to them which were then challenged by Bayer Corporation in IPAB. IPAB also supported the grant of compulsory license. This was again challenged before Bombay High Court.

**CONTENTIONS:**

- Bayer Corporation Contented that Natco did not approached in the prescribed manner and thus the grant of Compulsory License is not correct.
  The court denied this contention and stated that Natco had approached in a right manner. They did apply for voluntary license which was denied by you people.
- Further Natco contented that Bayer did not fulfilled the reasonable requirement criteria.
  Court looked into this contention and stated that Bayer supplied only 200 boxes of medicine which not sufficient to cure more than 8900 persons suffering from this cancer in India and thus there was a need for another supplier also.

[3] Natco Pharma vs. Bayer Corporation and The Compulsory License Regime in India
By: Mansi Sood

- Natco also contended that Bayer's medicine was not available at affordable price to the public at large. It costed more than Rs. 290000 per month whereas Natco drug was of Rs. 8800 per month.

**JUDGEMENT**

Thus the court gave its judgment in favor of NATCO pharma. This will serve to encourage other manufacturers to apply for compulsory licenses. The most obvious impact of this decision would be increased amount of applications for compulsory licenses. This decision will have a wide ranging impact on investments in pharmaceutical industry, research and development cost, trade relations and a variety of other related matters.

- **Bolar Provision: Flexibility of TRIPS.**

Bolar exemption acts like a defense for the generic manufactures. Under Indian Patent Law, Section 107A deals with this exemption which is in consonance with TRIPS by virtue of Article 30 which allows the member nations to impose restrictions on exclusive patent rights of the patentee. India being a developing country has a need of such provision to prevail so as to bring the stability in the economy.

Major reasons why it is important are:

- ✓ Bolar provision is necessary to promote market competition.
- ✓ It is necessary under pharma industry to make lifesaving drugs available at reasonable price.
- ✓ It also enhances the research and development.

The above discussed case for compulsory licensing found a new issue recently wherein Bayer found that Natco was exporting the product to some Chinese company for which Delhi High court also issued an interim injunction. Bayer contented that this act of Natco did not fall under the definition of Section 107A as it is not a party conducting Research and Development. The court found that the number of medicine being exported was activity. Court focused upon the plain meaning for the section which did not included sale outside India. Thus, the court stated that this section is applicable to a party when it exports the patented product to a third party outside the country with the intention of facilitating the research.

- **CONCLUSION**

Today, we have debates going on all over the world with regard to strongest patent system is owned by India. Whether product patent is right or not? Will it harm the research and development within medical industry? Nobody is able to provide a perfect answer to these existing questions.

Through the topics discussed above I come to the conclusion that every change has its own impact. Similarly granting of compulsory license or adoption of Bolar Provision may act as a hurdle to research and development but it has benefited the pharma industry and public at large.. India is a developing country and it needs a lot more technology and resources to attract more investors for research and development. On the other hand being a developing country it also has to ensure its public policy of keeping public health and thus when a medicine is not available to public at large at affordable prices the only solution left with the generic manufacturers are asking for compulsory licenses. To cope up with all kinds of problems of non availability of medicines when needed TRIPS flexibility act as the biggest help for the sufferers.