# Doha Declaration: Compulsory Licensing and Access to Drugs

Dr. Ajay Sharma

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## Abstract

This paper analyses compulsory licensing evolution phases and sheds light on reasons behind development especially after trade related aspects of intellectual property rights (TRIPS) provisions. Without patents, the innovators can neither be adequately compensated for their costs of research nor be encouraged for further research to develop new and improved products. Patent protection is therefore accepted as a necessary evil, despite its conflict with the competitions laws and human rights law (in case of pharmaceutical patents). Prior to Doha declaration pharmaceutical companies were enjoying the monopoly right because of patent protection regime for manufacturing, sale, and import the products which result into high cost of the patented products. Doha Conference on November 14, 2001 forced many countries to amend their patent rights for the purpose of compulsory licensing. This increased cost on patented molecules was a major hindrance for access to medicine. Public health officials considered Doha Declaration on compulsory licensing a positive approach in prioritizing public health over intellectual property rights. (Jain, 2009)

***Index terms***— TRIPS, compulsory license, patent.

## 1 Introduction

xclusive rights on innovations is permitted to an individual known as patent holder for twenty years who invents a useful or something new products or process. Patent holder enjoys a kind monopoly right which prevent him from exploitation on inventions. Government provides rewards in the form of royalty to the patent holder on efforts and skills which encourage further research and innovations. (Gupta, 2010) Research and development in pharmaceutical is very costly affair, unpredictable in nature and also time consuming process. Therefore patent on intellectual property rights to the innovator pharmaceutical firm is must, which may prevent patent abuse and allows competitor to enter into generic medicine market. (Kaur et al., 2015) Research and development in pharmaceutical patents provides patent holder a kind of monopoly rights. If patent holder is not compensated adequately for cost on research and development activity incurred on development of a new product leads to decline in research and development activity. Patent holder is compensated in the form of royalty for innovations on compulsory licence without permission from holder of patent. (Durojaye, 2011) "It is necessary to strengthen the system of compulsory licenses in the developing and least developed countries because of their inability/ inefficiency to cater to the needs of its people. And the granting of compulsory licensing over the patent protected drugs shall give monetary benefits to the patented pharmaceutical companies". Unites State criticized the implementation of compulsory licensing provisions because compulsory licensing policy reduces the benefits of further research and development. An individual under intellectual contribution on any research and development activity must enjoy the patent exclusive right. Monopoly right which is provided to the inventor has both the implications with regards to human rights law as well to the competition laws. Thus an effective mechanism is necessary to ensure the fair usage of the exclusive monopoly rights and compulsory licensing is one such safeguard. And granting of compulsory licenses to the developing countries on one hand can be least expensive and beneficiary to the people who are in need but at the same time it can incur heavy loss or put burden on the companies creating it but if it is seen from another point of view then it can be said that granting of compulsory licenses by paying the royalty to the originator company can make money to them which they would not be able to make it in the potential market due to the high prices. This review paper will deal with the issues related to

that and analyse the aspects where granting of compulsory license can be beneficiary to the inventors in cases of pharmaceutical companies.

## 2 II.

Research Objectives 1. To highlight the Doha Declaration and examine the relationship between the access to drugs and the employment of compulsory licensing. 2. To outline the Compulsory License regime in India and to ascertain the rationale and impact of the Judgment given by Supreme Court to Bayer Corporation v. Union of India. 3. To trace out whether the compulsory licenses for patent protected drugs is a necessary measure, or a threat to innovation. 4. To draw conclusions towards grant of compulsory licenses.

## 3 E b) Access to medicines and compulsory licensing

Though the TRIPS Agreement was proposed to address intellectual property rights as a trade related issue, the enforcement of the rule had sweeping connotations beyond the terms in which they were negotiated and adopted. Most of the developed countries developing countries under TRIPS excluded pharmaceutical products from patent protection. For example, Brazilian legislation amendment in 1969 declared pharmaceutical processes and products nonpatentable. India implemented process patent in year 1970, for pharmaceuticals which result into the development of a strong local pharmaceutical sector. Most of the countries feared that product patenting of pharmaceutical drugs would result in endangering affordability to general public. Moreover, the rationale of such a policy is to give space for the local industry to manufacture pharmaceutical product easily and without infringing. As said, the TRIPS obligate patent protection to pharmaceuticals. The monopoly granted to pharmaceutical industry resulted in high prices for medicines. In result, the right to the exclusive use of protected drugs excluding potential competition conflicted with the fundamental right to health, one more manifestation of which is the access to medicines needed by all. (Ford & Sara., 2000)

IV.

Cases of Pharmaceutical Firms What is a Compulsory License?

Compulsory licenses means license given by Government for manufacturing, use and sell a particular drug or for the use of a particular process to a thirdparty which has been invented and patented without permission from patent holder.

## 4 a) Compulsory license origin in india

After Independence Indian Government realized the need for the patent regime. Government of India formulated Tek Chand Committee towards the end of 1948, the committee known as Bakshi Report 1950, to check the pre existing Indian patent legislation for patent regime betterment. In year 1999 amendment was done first time in Indian Patent Act 1970, next amendment was done in year 2002 and 2005 subsequently. The third amendment in Indian patent act 1970 explored the development of voluntary licensing and change for the grant of voluntary license that are contained within the section 84 -92 of the Indian Patents Act 1970. Grounds for getting permission on Compulsory license is by writing an application under section 84 (1) to the patent controller after expiry of patent period which shall be three years from the date of the sealing of innovation on patent on the following grounds:

1. If affordable necessities of general public have not been fulfilled, 2. If innovation on patent is not worked within the territory of India, 3. If the patent invention is not accessible to the general public at an economic price. b) The salient features of compulsory licensing under the TRIPS Article 31 are:

? "Article 31(a) deals in the application for the issue of compulsory license shall be considered on its individual merits basis". ? Permission on voluntary license lies in the prior efforts made by applicant from patent holder on the basis of commercial terms and conditions which may be waived in the case of a national emergency or in the cases of public non-commercial use.

## 5 A Compulsory License may Additionally be Granted in the Following Ways

Section 92 A -"In Exports, national emergencies of general public for uncommercialized use by proper notification to Central Government in the official gazette".

Section 92 A (1) "To the countries in which pharmaceutical sector having light or insufficient producing capacity to handle general public health related problem".

Natco Pharma applied first for compulsory license in India for the producing Roche's innovation in the medicine named Erlotinib used in cancer and failed for export it to Nepal, then second application was made by Natco Pharma for the production of medicine named (Sutent) Sunitinib then again license was not again permitted.

On dated 9 March 2012, Natco received compulsory license for manufacturing Bayer's patented medicine named Nexaver in India by considering all the factors which were listed under section 84 of the Indian Patent Act 1970 on the grounds mentioned below:

1. Affordable necessities of general public have not been fulfilled, 2. Innovation on patent is not worked within the territory of India, 3. The accessibility on patent has not been fulfilled to the general public at an economic

price. Ministry of health in India on January 2013 allowed for production of generic medicine of the innovated firm i.e. three type's anti-cancer medicines namely dasatinib, trastuzumab, and Ixabepilone and selling them at an affordable price. (Chander et al., 2013) XI. Patented drug supplied into local market may create a kind of gray (illegal sale) market for many reasons. It is a situation when a drug is supplied into other market for which this policy was not designed and for sale on low prices than list price in the targeted market. (Christensen, 2012) This kind of marketing strategy is the contravention of the (IPR) Intellectual property rights. Where compulsory license for manufacturing of generic medicines provided to produce and for selling the innovated drug to market and the firm or their dealers sell the medicines to other country may lead to the patent abuse, which is seen in the case of license given for import of medicines. These medicines are known as counterfeit medicines which impose a heavy loss on health of public and patent holder. So gray (illegal sale) market requires a tight check while granting compulsory license. Pharma company dealers and the manufacturers are some time responsible for grey marketing situations and to avoid this situation medicine batch must contain a punch line "only to be sold in particular country" and "only for export". For Instance in year 2002 medicine named Procrit for treating anemia in cancer was a counterfeit medicine because of using non sterile water which results into major infections. **??**Yadav, 2015) XIII. Perspective of Compulsory Licensing Globally

# 6 Advantages of Compulsory Licensing

1. Increases in competition globally would result into reduction in prices due to which more generic companies would come into market to increase their share into market. So that patients can access economic medicines and compulsory licensing breaks up monopolies and cartels agreements sometimes and will save lives by ensuring accessibility of drugs at affordable prices. 2. Compulsory licensing will discourage research and development activity because it will make them dependent on the generic medicines because of low cost on investment as compare to cost on research and development activity. 3. Financially challenged patients: This development of compulsory licensing in developing countries would be useful for the poor patients for simple access and utilization to the medicines at low cost. Some pharmaceuticals gives free access to the medicines to the economically challenged people by launching programmes such as free access to the medicine within developing countries to shield their patent. Patent holder is compensated in the form of royalty for innovations on patent by Government for use of innovation in case of compulsory licence without permission from holder of patent. "It is necessary to strengthen the system of compulsory licenses in the developing and least developed countries because of their inability/ inefficiency to cater to the needs of its people. And while the granting compulsory licensing over the patent protected drugs shall give monetary benefits to the patented pharmaceutical companies". As India is a developing nation and also by considering the various important judgments pronounced by the Honourable Supreme Court of India relating to manufacturing of drugs at an economic rates, The Indian Government should promote process patent rather than providing product patent as it creates monopoly condition in the market which leads to higher price of drugs. Providing product patent is violation of various rights like public health and access to medicines, which ultimately violates the human rights of the individuals.

XV.

# 7 Conclusion

Developed countries Government limiting most developing countries not to issue compulsory licenses and expert from large pharmaceuticals feels that this policy would affect the research and innovation as patent holder would be unable to recover their amount invested in R&D activity. Opposite of this, NGO's has appreciated this policy of compulsory licensing on the perspective of good patient's health at an economic cost. In order to protect R&D and innovation, patent holder shall be compensated for developing the economic status of country, so this will help the innovator pharmaceutical company to shield their patents and accessibility for the developing countries. (Chander et al., 2013).The purpose of compulsory license lies in access to affordable drugs. Policies like drug price ceiling limit and control on profit margin on big pharmaceutical firm may control the patent abuse. With such policies general public shall access the medicines on an economic price. Countries foreign direct investment may get declined when country issue limits on the grant of compulsory license. Therefore government should put limit on compulsory license only in extreme cases in any country. Doha Declaration and Trade-Related Aspects of Intellectual Property Rights provisions give health benefits to the public on non discrimination basis. (Kaur & Chaturvedi 2015).The growing concern over compulsory license ultimately lies in country's urge to provide access to medicines at an economic cost. It is not disputed that voluntary licensing is potentially a powerful tool that developing countries including India can use to bypass patent laws and can provide their residents access to drugs mainly in some dangerous disease like cancer. Compulsory licensing breaks up monopolies and cartels agreements and sometimes provide their residents for access to lifesaving drugs at affordable prices. Though India is not at a stage to analyze the impact of first compulsory license, experiences of countries which granted such licenses shows that compulsory license has the potentiality to effectively reduce the price of the drugs and increase the accessibility of medicines. **??**Bale, 2005).There have been a handful of decisions that have the potential to foster the unique lines of Indian jurisprudence that projects access to essential medicines as a fundamental public health consideration. A unique provision that exists in Indian Patent Laws which prohibits patent for the use of known

## 7 CONCLUSION

substance throws light in the decision of Novartis Company Ltd. v. Union of India. **??**Cutler and Civil Appeal No. 2706 **??**2716

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Jurisdictional analysis 1. India Indian Patent Office has issued first compulsory license in year 2012 to pharmaceutical company named Bayer Corporation for innovation on cancer drug name sorafenib tosylate (Nexavar), which authorize NATCO a domestic generic medicine producer which also
( produce a low-cost version of the drug for two reasons mentioned below:
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Section 84 due to Unaffordable Prices and non Working of Patented Article Compulsory licensing are granted as following conditions 1) Prevent the patent abuse as a monopoly. 2) Commercial use of the patented inventions by an interested person. 3) Address the access of public health concern in India. VI. First Compulsory Licensing of Article 48 deals in Non-functional of the patent. 4. Provision in Indian Patents Act under Section 83 (f) and Provision in China for Patents Act under Article 48 deals in Anti-competitive practice by the patentee. 5. Provision in Indian Patents Act under Section 92 and Provision in China for Patents Act under Article 49 deals in Circumstances of national emergency or extreme urgency. 6. Provision in Indian Patents Act under Section 92 and Provision in China for Patents Act under Article 50 deals in Public health crises. 7. Provision in Indian Patents Act under Section 92 A Patent in India and Provision in China for Patents Act under Article
First compulsory license was given to Natco 50 deals in Export of patented drugs. Pharma Ltd. on 9 March 2012 by the patent office to manufacture generic version of Bayer Corporations medicines named Naxavar which is used in treatment of kidney and liver cancer. (The Intellectual Property Appellate Board) VII. Indian Patents act 1970's Main 8. Provision in Indian Patents Act under Section 91 and Provision in China for Patents Act under Article 51 deals in Licensing of related patents. 9. Provision in Indian Patents Act under Section 90(1) (vii) and Provision in China for Patents Act under Article 53 deals in Predominant use for the domestic market Features 1. Patent Act 1970 fills the gap between the patent holder rights towards society and his obligations. 2. Section 83 curbed the monopoly rights of patent holder. Patents are granted to encourage inventions not to enjoy monopoly rights and to accelerate domestic industrial growth. 10. Provision in Indian Patents Act under Section 84 (6) (IV) and Provision in China for Patents Act under Article 54 deals in Prior efforts of the applicant to

Tax benefits and some incentives shall be given to

holder of patent so that they can lower the price of

innovated medicines. Government

underdeveloped countries can encourage patent
holder for donation of patented medicines willingly.
(Yang, 2012)

Global Development of compulsory licensing practiced completely different view across globe. Unavaila-bility

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