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Doha Declaration: Compulsory Licensing and Access to Drugs

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Keywords: *TRIPS, compulsory license, patent.*

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Doha Declaration: Compulsory Licensing and Access to Drugs

Ms. Kiran Kumari [α] & Dr. Ajay Sharma [σ]

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)

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I. Introduction

Exclusive 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 on patent by government for use of innovation in case of 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.

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.

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Lord Macaulay law commission recommendations in 1856 first legislation came on patent.

Some important development of the patent regime is given below:

- Indian Patents and Design Act 1911. (Act II of 1911).
- Lahore High Court retired Judge Report 1950(Tek Chand Committee). This Committee Report 1950 led to the passing of The Indian Patents and Designs (Amendment) Act 1950.
- (Act No XXXII of 1950).
- Justice Rajagopala Ayyangar Committee Report 1959 on retention of Patent System. (Ayyangar, 1959).
- The Patents (Amendment) Act 1999. (Act 17 of the Patents (Amendment) Act 1999).
- The Patents (Amendment) Act 2002. (Act 38 of 2002. The Patents (Amendment) Act 2002).
- The Patents (Amendment) Bill 2003. (Bill No 92 of 2003 Lok Sabha)
- The Patents (Amendment) Act 2004. (Order No 7 of 2004 TRIPS compliance by 2005).
- The Patents Act 2005 amended. (The Patents Amendment Act 2005).

III. 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 third-party which has been invented and patented without permission from patent holder.

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) 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 non-patentable. 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

1. Novartis AG Pharmaceutical Company failed to win patent protection on medicine named Glivec whose application was rejected by Supreme Court of India. Many healthcare activists opinioned to Government for providing economic medicine, as branded or patented medicine are too costly to afford for poor people of the country. A report given by Novartis AG Pharmaceutical Company on economic medicines was that around sixteen thousand patients use medicine named Glivec and most of them received these medicines as free of cost. In the United State Pharmaceutical Industry trade group in research said that this compulsory licensing policy decisions are deteriorating environment for further research and innovations.

"*Protecting intellectual property is fundamental to the discovery of new medicines," the group said in a statement. "To solve the real health challenges of India's patients, it is critically important that India promote a policy environment that supports continued research and development of new medicines*."

This legal battle for compulsory licensing started when Supreme Court's denied for compulsory licensing in case of Pharmaceutical firm Novartis AG for a patent of drug named Glivec in 2006. (Kulkarni et al. 2013).The Battle for Compulsory license on patent regime was started in years 2006 and ended in year 2013 by the decision of Supreme Court in India. Novartis

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AG Pharmaceutical Company medicine named Glivec generic version of drug was the leading case for amendment in the Patent Act 1970 for Compulsory license on patent regime which forced Indian government to rethink over intellectual property rights on patent related issues. Novartis AG Pharmaceutical Company's product named Glivec generic version of drug failed in the tests of R&D, inventions under The Patent Act. However Novartis AG generic version medicine Glivec was granted patent in U.S, China and Russia, but was unable to fulfill the requirement of patentability of Indian Patent Act.

"*Indian Patent Act 1970's Section 3(d) deals in the discovery of any new property of new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant and Section 3(b) (an invention the primary or intended use of which would be contrary to law or morality or injurious to public health)".* These two sections 3(d) & 3(b) were the hurdle in Novartis AG Pharmaceutical Company's product named Glivec for which they did not received patent. (Ahmed, Taylor & Kumar, 2012 & 2013)

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:

a) "Production of generic version of medicine by NATCO a domestic generic company over Bayer Corporation named Nexavar that would be cost effective than the patented medicine and thus reducing monopoly over the drug in the Indian market."

b) "It may give an opportunity to other Indian generic drug manufacturer, if the innovator pharmaceuticals fail to supply patented medicine in large quantities at affordable prices."

2. *Case of Natco vs. Bayer. (Chaudhuri, 2002)*

- Bayer Corporation invented the drug Sorafenib in year 1990.
- Bayer Corporation in the United States applied for a drug patent in year 1999.
- Bayer Corporation launched the medicine under the brand name Nexavar in the market year 2005.
- Bayer Corporation received a patent for the drug in India year 2008.
- Indian drug Manufacturer Company named Cipla pharmaceuticals started selling of a generic version of Nexavar in year 2010.
- Generic manufacturer pharmaceutical firm based in Hyderabad named Natco pharmaceutical applied for a voluntary licensing to the patent controller of India for manufacturing generic version medicine under the name of Nexavar year 2011.

3. *Lee Pharma Limited vs. Lee Pharmaceuticals*

"*In June 2015, Lee Pharma filed an application for seeking the grant of a compulsory licence for manufacturing and selling the drug Saxagliptin used in the treatment of type-II diabetes mellitus. Saxagliptin is patented by Bristol Myers Squibb and marketed by AstraZeneca in India. The Controller rejected the application mentioning that applicant failed to satisfy regarding any of the grounds as specified in the section 84(1) of the Act*". (Lee Pharma Limited vs. Lee Pharmaceuticals on 8 May, 2017)

V. Grant of Compulsory License under 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 Patent in India

First compulsory license was given to Natco 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 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.
3. The Act allows process patents in food, medicines substances and drugs by chemical processes as health and food are important factors.
4. Patents Act 1970 under Section 53 provides protection of patent innovations up to a period of 14 years and in case of medicine it is provided for 7 years. This shorter period help the society just in case of monopoly as patentee may charge higher price.

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VIII. Provisions of Intellectual Property Rights

1. Article 27.1 enlarge the scope of product or Processpatent and also protects patent holder from discrimination on the basis of inventions, production and technology.
2. Article 33 extends patent protection period up to twenty years.
3. Under Article 31 limited compulsory licenses scope, government and for third party use. (Rana, 2018)

IX. Grounds for Compulsory License Issue

Compulsory License would be issued under following circumstances:

1) *Bayer Corporations Ltd failed to meet the general public need with reference to the patent invention and at the reasonably affordable price.*

Bayer Corporations Ltd. failed to fulfill the public requirements with regard to the drug access at the reasonably affordable price. Natco Company Ltd. on July 29, 2011. filed an application for issue of Compulsory License to the controller of patent in India for the manufacturing and sale of the generic version of patented medicine in India by its own brand name at price less than rupee ten thousand per month therapy against Bayer Corporations Ltd. who charged Rs.2, 80,428/- for one month therapy. The term affordable means general public purchasing power for the medicine. Division Bench of Bombay High Court held that of Pharmaceutical Company Bayer Corporations Ltd. did not adhere to the reasonably affordable price policy.

2) *Patented drug of Bayer Corporations Ltd (Nexavar) had not in the territory of India*

Under Article 27 of TRIPS: Bayer Corporations Ltd. argued that there can be no discrimination for the patented medicines, Manufactured or imported. Division Bench of Bombay High Court held that patent holder must perform some efforts for manufacturing of the drug in India. An argument made by Bayer Corporation Ltd. that the Compulsory license granted to Natco Pharmaceutical Company was against the conditions mentioned under Section 90. Adequate remuneration will be provided to the patent holder while granting voluntary license which is mentioned under TRIPS Agreement under Article No 31. Decision made on 9 March 2012 provided that 6 percent royalty was paid of total sales made paid by Natco Company Ltd. and reasons for fixing 6 percent royalty was that the petitioner failed to show the evidence for the cost incurred on inventions. Normal rate of royalty should be 4 percent as per United Nation Development Programme recommendations and by patent controller this royalty was again adjusted to 6 percent of the net sale. Further Tribunal has increased the royalty by 1 percent i.e. up to 7 percent of net sales made by Natco Company Ltd. The petitioner failed to show in what manner the royalty was fixed at 7 percent. (Chandiramani, 2002)

a) Indian and European Countries provisions on compulsory license

1. "Export of innovative pharmaceutical medicinal products under paragraph 6 decision in Doha Declaration deals under Section 92A in Indian and regulation No (EC) 816/2006 in Europe".
2. "Mandatory cross-licensing between the owners of patented biotechnology inventions and registered plant variety under Directive 98/44/EC provisions in the European regulations".
3. Provision in Indian Patents Act under section. 84 (1) (c) and Provision in China for Patents Act under 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 and Provision in China for Patents Act under Article 50 deals in Export of patented drugs.
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
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 obtain a voluntary license is necessary.
11. Provision in Indian Patents Act under Section 94 and Provision in China for Patents Act under Article 55 deals in Termination of the compulsory license.
12. Provision in Indian Patents Act under Section 90 (1) (iv) and Provision in China for Patents Act under Article 56 deals in Non-exclusive basis
13. Provision in Indian Patents Act under Section 90 (1) (i) and Provision in China for Patents Act under Article 57 deals in adequate remuneration to the patentee.
14. Provision in Indian Patents Act under Section 117 A and Provision in China for Patents Act under "Article

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58 deals in Decision on compulsory license subject to judicial review". (Mathur et al., 2016)

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.
- "Compulsory license shall be issued on non-exclusive basis given in Article 31(d)".
- "compulsory license shall be granted for the purpose of availability of medicines only in the domestic market of the country who will issue the license [Article 31(f)]";
- The holder of patent must get enough remuneration on the basis of expenditure made by him. [Article 31(h)];
- "The compulsory license shall be under legal validity and any decision related to license will be subject to judicial review in the country who issues the compulsory license [Article 31(i) and (j)]".
- Member of World Trade Organizations conference in Qatar on 14 November, 2001 adopted the "Declaration on the TRIPS Agreement and Public Health". (WTO Ministerial Conference Doha, 2001)

X. 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. Advantages of Compulsory Licensing

1. Compulsory licensing breaks up monopolies and cartels agreements and sometimes provide their residents for access to life-saving drugs at an affordable price.
2. It helps in economic growth and technological advancement of the country.
3. It encourages research and development activity.
4. It is argued that compulsory licensing helps in developing a local generic pharmaceutical market. (Bayer Corporation vs. Union of India, 2014)

XII. Disadvantages or Consequences of Compulsory Licensing

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)

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XIII. Perspective of Compulsory Licensing Globally

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.
4. Development of compulsory licensing practiced completely different view across globe. Unavailability and unaffordability of the medicines in most developing countries are major issues for the grant of compulsory licensing policy. Opposite of this developed and underdeveloped countries putting pressure on developing countries like Europe and United State for non issuance of compulsory license as a reason that it would lower the research and development activity. China in year 2012 conjointly had opened the manner for generic version of medicines by creating a change in Intellectual property laws and this allowed china government to permit compulsory licenses for manufacturing generic version of medicines which would be economic to general public use. Zimbabwe in year 2003 issued its first compulsory license to Varichem Pharmaceutical Co. which is a local generic pharmaceutical firm to manufacture anti retroviral medicine for low income people. Compulsory License issued by Indian pharmaceutical Company Cipla to the countries namely Malaysia, Indonesia, Mozambique, and Zambia in year 2004 for the import of anti retroviral medicines for a period of two years. Indonesia has allowed using compulsory license for anti retroviral medicines named lamivudine and nevirapine. Mozambique country issued its generic version of medicine for HIV/AIDS drugs. In year 2005 Ghana and Eritrea country issued its generic version of medicine for anti retroviral medicines HIV/AIDS drugs respectively. In Year 2006 and 2007 Thailand, Rwanda and Brazil issued its generic version of medicine for curing heart disease by use of drug Plavix and Brazil country allowed for the import of generic drug Efavirenz from India. Also Rwanda country allowed for compulsory license in the form of Nevirapine, Zidovudine and Lamivudine named Triavir to treat HIV and AIDS which they were unable to manufacture locally. Natco Pharmaceutical a domestic generic medicine producer received first compulsory license in year 2012 for manufacturing Bayer Pharmaceutical's invented drug name Nexaver. (Chander et al., 2013)

XIV. Some Measure are Proposed to Strengthen the Compulsory License Regime in India as given below

1. Corporate social responsibilities:-Indian government shall have good joint efforts with most big pharmaceutical companies as an involvement in government funded healthcare mission in the form of corporate social responsibilities which would encourage them as an equal partner and by this way they can reduce the chances of patent abusing.
2. United State Act on intellectual property for protection of patent through government funding named Bayh-Dole shall be enforced in India, which may allow the Indian Government to grant compulsory licenses on inventions in some cases.
3. Indian Government shall exercise pressure on the innovation to the patent holder which may cut the price of the innovative product or may purchase innovated medicines from the producers of patent by drug price control mechanism or by negotiations.
4. Indian Patent Office must issue guidelines related to issue and interpretations of compulsory license which would result into reduction in ambiguity on provisions of compulsory license.
5. Low royalty & royalty free method: Compulsory license for manufacturing of generic version of patented drug are issued in crisis, emergency or on urgent basis when the drug is required on large scale and on economic price so medicine should be within the reach general public. Royalty in case of crisis, emergency or on urgent basis shall not be high as the burden of this would come on general public in increased price for. Marketing geographical location, quantity of product, time period of license, market value of product, and percentage of customers are the factors which shall decide the percentage of royalty. Countries of high & middle income group shall be paid high royalty for compulsory license because of low disease rate and vice versa. Compulsory license given on royalty free basis will result into decline of efficacy and production skills on patent inventions for further development of research & development. Society will be benefited when same medicines are

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available into the market, its prices would be less because of perfect competition into that area. Royalty for efforts to holder of patent must paid in reasonable amount with proper negotiations skills and by proper agreement. In case of critical illness drugs like cancer, AIDS, tuberculosis government shall purchase the patent from the holder of patent. Tax benefits and some incentives shall be given to holder of patent so that they can lower the price of innovated medicine. Government in underdeveloped countries can encourage patent holder for donation of patented medicines willingly. (Yang, 2012)

6. 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 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. 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 life-saving 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 substance throws light in the decision of Novartis Company Ltd. v. Union of India. (Cutler and Civil Appeal No. 2706-2716, 2013)

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