COMPULSORY LICENSING IN INDIA A: COMPARATIVE STUDY WITH USA AND UK

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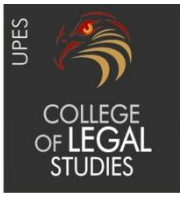
THIS DISSERTATION IS SUBMITTED IN PARTIAL FULFILLMENT OF THE DEGREE OF B.B.A., LL.B. (Hons) OF COLLEGE OF LEGAL STUDIES, UNIVERSITY OF PETROLEUM AND ENERGY STUDIES, DEHRADUN



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CERTIFICATE

This is to certify that the research work entitled **"COMPULSORY LICENSING IN INDIA A: COMPARATIVE STUDY WITH USA AND UK"** is the work done by **MADHUR AGRAWAL** under my guidance and supervision for the partial fulfillment of the requirement of **INTEGRATED B.B.A., LL.B. (Hons) degree** at College of Legal Studies, University of Petroleum and Energy Studies, Dehradun.

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DECLARATION

I declare that the dissertation entitled **"COMPULSORY LICENSING IN INDIA A: COMPARATIVE STUDY WITH USA AND UK"** is the outcome of my own work conducted under the supervision of **Ms.CHARU SRIVASTAVA**, at College of Legal Studies, University of Petroleum and Energy Studies, Dehradun.

I declare that the dissertation comprises only of my original work and due acknowledgement has been made in the text to all other material used.

Madhur Agrawal

9/4/2015

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ABBREVIATIONS

EPO -EUROPEAN PATENT ORGANIZATION

CL- COMPULSORY LICENSING

TFA-TECHNICAL AND FINANCIAL ASSISTANCE

WIPO0- WORLD INTELLECTUAL PROPERTY RIGHT ORGANIZATION

GATT- GENERAL AGREEMENT ON TRADE AND TRAFFIC

TRIPS- TRADE RELATED ASPECT OF INTELLECTUAL PROPERTY

WTO- WORLD TRADE ORGANIZATION

IP- INTELLECTUAL PROPERTY

CH. –CHAPTER

SEC. - SECTIONS

ART. –ARTICLE

USA-UNITED STATES OF AMERICA

UK- UNITED KINGDOME

EU-EUROPEAN UNION

TABLE OF CASES

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I **MADHUR AGRAWAL** take this opportunity with much pleasure to thank all who have helped me throughout to prepare this dissertation report. I sincerely thank my mentor Ms. **CHARU SRIVASTAVA** for her guidance motivation and support.

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1 INTRODUCTION

The concept of intellectual right is based on the person who has gave his contribution has exclusive right to enjoy the fruit of his labour and hard work which he has gave to create such IP. Intellectual property is a legal term which denotes creation of mind which are created by the owner by putting his hard labour in it and the owner is granted certain exclusive rights to use it which is called intellectual property right and are intangible property. An IP holder has exclusive right over its creation and can use it in the manner he want, he can lean his right to someone, he can sell his right, or he can pass away his right to use that IP to someone it's his discretion. But there are certain exception to this rule even if a person owner of IP don't want to use his right his work can be bought into ambit of compulsory licensing if the government think it's useful for the public at large or something necessary for protecting the interest of people at large.

An compulsory licensing can be imposed on any IP particularly copyright or patent either by law or by mutual consent. If it is imposed by law the remuneration so will be paid will be decided by the court. It is an exception to the concept of Intellectual property right.

1.1 Compulsory licensing

A compulsory license can be defined as allowing the third party to sell, make, or use an invention which is patented by a person without the patent holder consent. Under Indian Patent Act, 1970, the provision of the compulsory licensing is provided under Chapter XVI. Globally also the concept of compulsory licensing is well recognised while keeping community interest at large

A **compulsory license** is an authorization given by the authority of the nation where it is patented, without the permission of the owner or titleholder, for the exploitation of the patent protected under patent act.

Compulsory licensing denotes that a person who is non-patent holder can use an IP created by an IP owner without the consent of patent holder by paying him certain remuneration if such patent is necessary for the public at large or can improve the social condition of the people.

A compulsory license is an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the state. All across the world the compulsory license on IPRs is granted on almost similar grounds like unreasonably exorbitant prices of an essential facility or commodity; or patent being not worked in the country; or where substantial public interest is affected by the way IPR holder is exercising its right. Antitrust violations have also been reprimanded by awarding compulsory licenses in some jurisdictions where there has been abuse of IPR leading to exclusion of competitors in an industry.

The compulsory licensing has been mandated by several international organizations and convention like WIPO, Paris Convention for the protection of industrial property and WTO Agreement on TRIPS. These international agreements have given several grounds to their contracting states to like promotion of public health and nutrition or to promote the public sectors of vital importance to their socio economic and technological importance.

In anti-trust violation also the compulsory licensing may be resorted to as a remedy where patent has been abused or where the protected product is vital to national interest or the licensee getting the compulsory license is the government. Therefore, there are situations where we see the interest of society at large more important and give more importance to it then personal rights in the form of IPRs.

Lots of countries have issued compulsory licenses for anti-competitive misuse by the companies in matter related to IPR. According to a survey around 55 countries in the world have given compulsory licenses after the TRIPS agreement came into force. Several countries like Brazil, Thailand, Africa, Malaysia Kenya, and Ecuador have issued compulsory licenses over the patent drugs right and recently India has joined the wagon of compulsory licensing when the Patent Controller awarded compulsory license on a cancer drug patented by Bayer to generic drug maker Natco Pharma. Indian Patent law has provisioned for compulsory licensing since early days of enactment in 1961.

Statutes are present to enforce compulsory licensing, still debatable to secure the interest of title holder.

Patents are here to promote innovation and development. If these are not protection by govt., no firm would invest so much in it to develop a new product. If other firms are allowed to copy the

same products invented by the other firm, there exists no monopoly and prices would automatically come down. Patent is not a perfect mechanism for the protection of IP, but it is necessary when it is required for the public at large to improve the socio economic condition of the people to the country.

World Trade Organization, in its Doha Declaration, Right to access the affordable medicine was recognised. Lifesaving drugs like medicine for cure of cancer or HIV are way beyond the purchasing power of common man and should be available to them at reasonable prices. The availability of such lifesaving drugs becomes even more uncertain when there is national emergency. Doha deceleration does not only talk about national emergency for the grant of compulsory licensing but it provide freedom to its member states to determine grounds of compulsory licensing.

Compulsory licensing involves breaking of the exclusive right of the patent holder or the IP holder of the product. The purpose behind breaking of the patent right is to change the terms of bargaining between the buyer and the seller. For instance, if the government is a buyer and the patent holder is a seller, and the parties fail to negotiate a reasonable price of the product, compulsory licensing provisions provide for an arrangement using which the government may dilute exclusive patent right of the patent holder and license some other firm to sell the same product. Compensation is, however, paid to the patent holder in exchange for use of his patent.

It is important to note that access to drugs or to deal with emergency public health situations is not the only reason for grant of compulsory license. It can be used as a policy mechanism to deal with anti-competitive practices, non-working of the patent, or other undesirable behavior of patent holders. Compulsory license not only forces the patent holder to use his invention for the benefit of the society but also boosts generic industry of the country granting such license.

It's not easy to reach an conclusion on the matter related to compulsory licensing. The developed nation keep monitoring the grant of licenses whereas developing nation keep on arguing for the need of additional monitoring body for the grant of compulsory licensing. The powerful lobby of the US pharmaceutical industry keep on monitoring it ,The USA revoked the status of most favored nation until the changes are made in the patent law. Hence in the year 1994 TRIPS was

created to look for the benefit of developing and developed states and it was the biggest achievement as it was able to bring a meeting point for both the states.

For the protection of IP, keeping in view the above mentioned statement, the countries can be divided into two groups whose behavior is totally different depending on interests of each group. It is a notable that the developing and under-developed countries does not have so much resources and still their half of the population is struggling for a day mealand hence they are not so much concerned about protection of IPRs and are not willing to spend on development of an any mechanism for the protecting of IP. There are various reasons behind this intentional casual approach towards protection of IPRs.

1. IF the Prices are less the developing and underdeveloped countries can ensure availability of needed basic service required, goods to their citizens at affordable prices making their life easy.
2. The local industries produce counterfeit goods, and provide employment to thousands of employee and can reduce the unemployment in the country.
3. It also help the developing country advancing them in science and technology, as third world countries need maximum access to intellectual property of advanced nations.[1]
4. The Patents in underdeveloped and developing countries are owned by citizens of a developed countries and the total amount to more then 80%. Consequently, the developing country does not have any interest in enforcing the right of the developed country for the protecting of IPs created by company of their nation.[2] Developed countries, development and progress very much depend on the protection of IP, it depends on and investment in research development. Their patent system provides incentives to speed up their technological progress, enhance their productivity, and improve their world trade position by strengthening their economy.[3]

[1] G. J. Arnold, "International compulsory licensing: the rationales and the reality," PTC Research Foundation of the Franklin Pierce Law Center, IDEA: Journal of Law and Technology, vol. 5, 1993
[2] ibid
[3] R. Gottschalk. Vital Speeches of the Day. [Online]. 21. Available: http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=28&hid=12 2&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13

The countries which granting the compulsory licensing provisions are criticized by the US and the foreign MNC because the licensee remove the benefits of other's research without contributing their fair share to the costs incurred on research and development.[4]

This does not mean that there are no arguments in favor of compulsory licensing. Some are as under:

1. Patents, especially to pharmaceuticals, are harmful to developing and under-developed countries lacking their own domestic and technical infrastructure; patents may become an impediment in economic growth of such countries and availability of necessities to population of such countries. Threat of non-voluntary licensing may be helpful in negotiating a reasonable price of the needed drug acceptable to both the patent owner and the government.[5]
2. Allowing compulsory licensing to pharmaceutical patents help the people by availing them the lifesaving drugs at affordable prices; it can be used to prevent the monopoly and cartel to protect the patent rights.[6]
3. Sometimes delay in development of important technology is caused due to deadlocks between the improver and the original patentee. The broad Edison lamp patent slowed down progress in the incandescent lighting field. Compulsory licensing can be used as an effective tool to resolve these deadlocks by pressurizing the original patentee to come to the terms of an agreement with the improver. It can therefore help in generating rapid technical progress.[7]
4. By incorporating an mechanism of Licensing, developing countries Govt. may pressurize the patent holders to work the patent in the favor of nation development. [8]
5. Compulsory licensing is necessary where the refusal by the owner can lead to harm the technological advancement or economic growth of a country.[9]

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[4] G. J. Arnold, "International compulsory licensing: the rationales and the reality," PTC Research Foundation of the Franklin Pierce Law Center, IDEA: The Journal of Law and Technology, 1993
[5] J. Kuanpoth, Proceed with caution on compulsory licensing, pp. 26, 2011
[6] Jenkins, Compulsory licensing: a major IP issue in international business today? pp. 371.
[7] U. S Centennial of Flight Commission. Glenn Curtiss and the Wright Patent Battles. [Online]. Available: http://www.centennialofflight.gov/essay/Wright_Bros/Patent_Battles/ WR12.htm,
[8] J. A. Yosick, "Compulsory patent licensing for efficient use of inventions," University of Illinois Law Review, 2001.
[9] G. J. Arnold, "International compulsory licensing: the rationales and the reality," PTC Research Foundation of the Franklin Pierce Law Center, IDEA: The Journal of Law and Technology, 1993.

6. The proponents of compulsory licensing argue that compulsory licensing does not discourage research and development because the costs incurred on research are recovered from sales of the patented products in the advanced states of the world having stringent patent protection.[10]
7. It is argued that compulsory licensing plays a vital role in developing and fostering a local generic pharmaceutical industry.
8. Apart from economic arguments, use of compulsory licensing to protect the public interest can be defended on social justice grounds; strict adherence to patent protection can hardly be recommended at the cost of human lives. Despite criticism and drawbacks of compulsory licensing, the right of sovereign states to grant a compulsory license has been effectively recognized at international level. Since patent is a privilege granted to the patent holder by the state, government of the state can therefore limit that privilege in certain situations? This is the basic rationale for compulsory licensing. The concept came to the limelight after outbreak of pandemics like HIV/AIDS as the issue of access to necessary drugs emerged as an important global issue. The dilemma of patent rights versus patient rights deserves a detailed analysis.

Although TRIPs emerged from vivid negotiations, there were high hopes for multilateral methods to trump bilateral bullying. At the onset, it was apparent that TRIPs initially would cost developing countries money,' but it also was speculated that the long-term benefits would help nurture the emergence of pharmaceutical industries in developing countries to ultimately reduce the cost of pharmaceuticals." Although TRIPs incorporates portions of the Paris Convention, the

Berne Convention, the Rome Convention, and the Treaty on Intellectual Property in Respect of Integrated Circuits," the patent provisions are notably new to international intellectual property law.'" Without terming it such, TRIPs allows for compulsory licensing amidst several provisions in Article 31.

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[10] [24] J. Kuanpoth, Proceed with caution on compulsory licensing, pp. 58, 2011.

1.2 Grounds for the grant of a compulsory licence in India

The current system of compulsory licensing for patents in India is provided under chapter XVI of the Patents Act 1970 comprising Sec. 82 to 94.

The grounds on which a compulsory licence can be granted under the Patents Act 1970, can be sub-divided into the following categories:

1) Abuse of patent rights, dealt with broadly under s 84.
2) Public Interest', dealt with broadly under s 92.
3) Other provisions on compulsory licensing such as s 91, dealing with the licensing of related patents.

1.3 PROCEDURE FOR GRANT OF COMPULSORY LICENCE.

This section explores the procedure for obtaining a compulsory licence under The Patent Act, 1970 as amended on 2002

Under each section, the procedure has been detailed under the following heads:

(1)Who grants a compulsory licence.

(2)Who may apply for the compulsory licence.

(3) Outline of the procedure involved.

1.3.1 Who Grants a Compulsory Licence

The Controller General of Patents and Trademarks and copyright has the exclusive authority to grant a compulsory license under the Patents Act 1970[11], An appeal lies from the decision of the Controller to the Intellectual Property Appellate Board which is provided under section 83 0f trademark act of 1999.

1.3.2 Who May Apply For Compulsory Licence

Any person interested may apply for a compulsory license under Section 84 of the Patents Act as provides .Now 'person interested' is the question is?

a) Person Interested

The definition is inclusive and thus wide in scope. The term 'any person interested' has, however, defined under s 84(2). Section 84(2) provides that a person who is a licensee under the patent, will not, (on that ground alone), be debarred from making an application for compulsory license before the Controller.

Courts have also interpreted the term widely. In Neo-Pharma Industries v Park Davis and Co the Controller held that the fact of infringement only goes to show that the applicant is a 'person interested'.

However, person interest not a ground for the grant of compulsory license in India. Rather, a number of conditions have to be complied with in order to be considered eligible for the grant of a compulsory license. Section 84(3) states that an application for compulsory license under s 84(1) must contain a statement setting out the 'nature of the applicant's interest', together with such particulars as may be prescribed and the facts upon which the application is based.

b) **Eligibility Criteria**

Section 84(6) lays down the considerations that the Controller must take into account while dealing with an application for compulsory license. Section 84(6)(ii), (iii) and (iv) provide that while considering the application for compulsory license, the Controller must take into account

[11] Controller General of Patents, is appointed under s 3(1) of the Trademarks Act 1999

'the ability of the applicant to work the invention to the public advantage', '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 efforts to obtain a license from the patentee on reasonable terms and conditions, and such efforts have not been successful within a reasonable period.

c) Compulsory License for Research

Notwithstanding the fact that there is a research and experimentation exception within the Indian patent law, 85 it may be pertinent to consider here whether a person/entity doing mere research is eligible for the grant of a compulsory licence.

As per the definition under s 2(t) of the Patents Act, a person engaged in or promoting research in the same field as that to which the patent relates, is a 'person interested', and such person may apply for grant of compulsory license under s 84.

However, in the light of s 84(6) (ii), the Controller would consider whether the applicant has 'the ability to work the invention to the public advantage' and whether the 'applicant has the capacity to undertake the risk in providing capital and working.' Because a mere experimentation or research related use may not amount to 'working' the invention in its ordinary sense, it is unclear whether a compulsory license would be granted to an applicant who merely wishes to conduct research on/with the patented article, especially if such research is undertaken for commercial benefit.

2 ORIGIN OF COMPULSORY LICENSING

The compulsory licensing concept is not a new concept. This concept was first time incorporated in England for protection of monopoly in 1623 and became popular in 18th century and with the passes of time it became an important feature of the IP right.

Patent was a part of IP even before the 17th century though there was no law governing in that era. Earlier the state don't have any priority to enforce patent law and their exist a weak patent laws. It was 1990 after when the technology grew up and IP emerge as the major concern for the developed and developing nations

WIPO was, established in 1967 even prior to WTO with an aim to protect intellectual property and to encourage the creativity in the work or invention, and it was the sole international organization who was dealing with intellectual property right in world. It bought harmony in the procedure of the states that are part of this organization and IP legislation. After the formation of WIPO under it not only various new treaty was concluded but old treaty was also revised under it . Berne was for the protection of literary and artistic works held in 1886 and Paris convention for the protection of industrial property 1883 are the two treaties who got revised under WIPO.[12]

Patent holder's right to control, usage, price, and supply was recognized globally much earlier, but recognition of this right was confined to patentee's home country. There was no procedure to protect the right of the citizen in another country. The primary objective of the Paris convention was to develop a system at international level using which inventors could protect their innovations globally , Paris Convention provided for licensing involuntary in order to prevent abuse of exclusive patent rights under Article 5(a)(2) of the convention, purpose of the allowing the member state to grant compulsory licensing is the use the patents which not utilized to their effect, Article 5(a) (4), however, also provide that if the patent has legitimate use the compulsory licensing should not be done. This right was there to avoid chances of abuse of the right which was given to the patentee in 1925 when article 5(a) of the Paris convention was revised.

Paris convention was controversial because it was too vague and broadly defines the "Abuse" of the patent, for instance the vague undefined word was open to broad interpretation which as not needed. Paris convention does not define all the key terms but it leave it be defined by the member states. Paris convention, however, contributed towards evolution of minimum international standards regulating intellectual property protection. Despite the demerits of the

[12] The World Trade Organization (WTO) is the only global international organization dealing with the rules of trade between nations. It intends to supervise and liberalize international trade. The organization officially commenced on January 1, 1995 under the Marrakech Agreement, replacing the General Agreement on Tariffs and Trade (GATT).

convention, this was a successful treaty[13] that survived for more than 130 years and has more than 150 countries party to it.

Bern convention came into force in the year 1886 is another important international treaty for the protection of copyright and which was revised by WIPO after 1969. The Berne convention Article 11 provided for compulsory licensing in case of broadcasting and related rights. Same as article 13, of the Berne convention talk about granting of compulsory licensing in the case of musical work.

India being a developing country in 1967 argued that there should be no restriction in granting a compulsory licensing if demand arise in the country. Other countries like UK, USA opposed it and said that the compulsory licensing cannot be granted a not inventor by harming the author. The expense of authors should be given proper credit before any such measure is taken. The **Stockholm Protocol** failed because it did not able to bring any compromise between both the blocks.

Compulsory licensing provisions were extremely disturbingly, complicated, ambiguous with the strict conditions for the grant of compulsory licensing and it did not able to fulfill the purpose of developing country (poor countries).

To centralize the international trade issues, the General Agreement on Trade and Tariffs was created in the 1940s. It has 92 states party to the agreement who followed the GATT guideline, these states followed the guidelines created for the trade related aspect created by the gate till 1989. The GATT laid the foundation of the World Trade Organization (WTO) was established as a separate and viable organization having members from least developed developing and developed nations. GATT basically focus on the trade in good whereas the WTO focus on tade in services like IPR.

2.1 A BRIEF HISTORY OF COMPULSORY LICENSING PROVISIONS UNDER THE INDIAN PATENT REGIME

[13] Paris Convention is still in force as of February 2013.

To see the present compulsory licensing regime, it is important that we go back a little in time.

In 1856 first patent legislation of India came into force.[14] Which granted exclusive privilege for the period of 14 year? In the year 1911 the Indian Patents and Design Act came into force. Some of the important milestones in the development of the patent regime in India may be enumerated as follows:

1) The Indian Patents and Design Act, 1911
2) The Tek Chand Committee Report. This report led to the passing of The Indian Patents and Designs Act, 1950
3) The Ayyangar Committee Report. This report finally led to the enactment of The Patents Act, 1970.
4) The Patents Act, 1970

With the above mentioned changes compulsory licensing has seen the notable changes which are:-

(1) <u>The Indian Patents and Design Act 1911.</u>

The Patents Act 1911 established for the first time a system of patent administration under the management of the Controller of Patents. This Act provided for the grant of compulsory licensing mainly in the case of misuse or abuse of patent rights. Under this Act, any interested person could, after the expiration of three years of the sealing of a patent, apply to the Controller of Patents for the grant of compulsory licence, on any of the following grounds:[15]

(a)That the invention which is patented in India should have worked to its fullest , has not been commercially worked or is not able to work to its fullest as it should have been worked.

(b) That a demand for the patented article in India is not being met to an adequate extent or on reasonable terms, or is being met to a substantial extent by importation of the patented article from other countries;

[14] See P Narayanan, Patent Law,third edn, Eastern Law House, 1998, p 4.
[15] Sudip Chaudhuri, 'TRIPS Agreement and the Amendment of Patents Act in India', Economic and Political Weekly, 10 August 2002, p 8

(c) That by reason of the refusal of the patentee to grant a licence on reasonable terms, a market for the export of the patented article manufactured in India is not being supplied.

(d) That by reason of conditions imposed by the patentee upon the grant of licenses under the patent, or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent or the establishment or development of commercial or industrial activities in India is unfairly prejudiced.

After independence, the Indian government felt that a patent regime that had been devised under the British rule needed substantial restructuring to bring it in line with the aspirations of an independent country. Towards this end, the Government of India appointed the Tek Chand Committee in 1948 to specifically examine the existing patent legislation with a view to improving it.

(2) Tek Chand Committee Report and the Patent Amendment Act 1950

The fundamental strategy adopted by the Tek Chand Committee in its analysis of the existing legislation, was to defend the 'public interest' in availability of food and medicine by examining inter alia, an effective system of compulsory licensing for 'food and medicine' related inventions.[16] The Committee felt that the existing provisions in the Patents Act 1911 were inadequate to deal with patent abuse.

The final report was substantially based upon the recommendations made in the Patents and Designs Bill 1949 pending in the UK Parliament at that time. The key suggestions were that compulsory licenses could be applied for after three years, by making an application to the Comptroller General on grounds that included the following:

i) Commerce/industry in India was being substantially affected;
ii) Export in the patented item was absent; and

[16] Rajeev Dhavan, Lindsay Harris & Gopal Jain, 'Whose interest? Independent India's Patent Law and Policy' Journal of Indian Law Institute, vol 32, 1990,p 433

iii) Manufacture or market of other patented items was adversely affected rather than simply assert that the manufacture was taking place outside India and the applicant was able and willing to work the patent in India.

It is pertinent to note that most of the above changes were affected through the 1950 amendment to the Patent Act 1911, before the final report of the Tek Chand Committee Report was released. In short, as a result of this report, the grounds for compulsory licensing widened.

The main addition to the existing grounds was that a compulsory licence could be requested if:

i) Due to the conditions imposed upon the use of a patent or a sale of a patented article, commercial or industrial activities were being hampered.
ii) The Government of India felt that this would be in the interests of consumers or the industrial development of the country. The government could also apply for a compulsory licence to be granted to it in order to enable private parties to work the patent.

The provision enabling the government to request a compulsory licence on behalf of private parties seems to suggest the inclusion of a 'public interest' ground. In this regard, the Tek Chand Report went beyond the 1911 Act, under which the compulsory licence provisions mainly catered to instances of patent abuse.

However, even this new regime did not prove to be very effective as the provisions were fairly cumbersome when it came to their actual application.

(3) The Ayyangar Committee Report

Like the earlier committees, the Ayyangar Committee was appointed to see the legislations needed for the protection of the patent holder right in the future . This Committee widened its scope of examination and came up with certain valuable suggestions.[17] The Ayyangar Committee found that foreigners held 80-90 percent of Indian patents and that more than 90

[17] R Ayyangar, 'Report on the Revision of the Patent Law', New Delhi, 1959, p 60.

percent of these patents were not even worked in India.[18] The Committee concluded that the system was being exploited by foreigners to achieve monopolistic control over the market, especially in relation to vital industries such as food, chemicals, and pharmaceuticals, which was the real area of controversy. Medicines were arguably unaffordable to the general public, and the drug-price index was rising rapidly. As the Committee observed, the provisions regarding compulsory licensing were 'wholly inadequate to prevent misuse or abuse of patent rights, particularly by foreigners'. The report enumerated some of the reasons for the fairly minimal number of compulsory licenses granted under the previous regime. Briefly, they include the following:

i) The deterrent effect of 'compulsory licensing' provisions may have encouraged a large number of voluntary licenses. However, this could be a mere surmise, as there was no statistical information available at that time to test the same;

ii) The narrow nature of the grounds upon which a compulsory licensing application could be agitated;

iii) Lack of transfer of know-how from the licensor to licensee. It must be remembered that compulsory licensing provisions do not mandate a transfer of know-how;

iv) The fact that most of the licensor's products were branded. Consequently the licensee found it difficult to compete with these internationally well-known brands.

Owing to these various reasons, Ayyangar J recommended changes in the compulsory licensing regime. The suggestions made by the Ayyangar Committee went on to form the basis for the unamended Patents Act 1970.

(4) The Patents Act 1970

As mentioned above, the Ayyangar Committee Report finally resulted in the Patents Act 1970. In order to comply with TRIPS the Patent act of 1970 Act was amended thrice, first in 1999, then in

[18] MJ Adelman and S Baldia, 'Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India', Vanderbilt Journal of Transnational Law, vol 29, 1996, p 507.

2002 and again in 2005. In between the second and third amendments a Bill was introduced in the year 2002 and 2004 which later lapsed owing to a change in government.

The grounds on which a compulsory licence can be granted under the Act can be sub-divided into the following categories:

(i) Abuse of patent rights (dealt with broadly under Sec. 84);

(ii) 'Public Interest' (dealt with broadly under Sec. 92). Apart from the above mentioned broad categories, there are other provisions on compulsory licensing such as Sec. 91, dealing with the licensing of related patents. All these provisions will be discussed in greater detail under the heading 'Grounds for the Grant of a Compulsory Licence.'

3 ORGANIZATIONS AND TREATIES

Compulsory licensing is older concept which originated in 16th century and developed in 19th - 20th century Treaties like Paris convention and Bern convention which talk about protection of Copyright and Patents played an important part in development of compulsory licensing. Organizations like WIPO acted as a regulatory organization that ensured the implementation of its laws in the signatory countries. Whereas TRIPS provided the short-coming in Compulsory laws so as to make it easier for countries to implement it for both developed or developing nations.

3.1 PARIS CONVENTION, 1883

The Paris convention was the first convention came into existence in 1883 and 11 countries signed the treaty in Paris, after a diplomatic conference in the year 1880, it was one of the first intellectual property treaty. It was established with the aim to protect industrial property and patents, trademark and form act as a middle man between the two countries, this treaty is still in force till 2014.

The Treaty was revised at Brussels, Belgium, on 14 December 1900, at Washington, United States, on 2 June 1911, at The Hague, Netherlands, on 6 November 1925, at London, United Kingdom, on 2 June 1934, at Lisbon, Portugal, on 31 October 1958, and at Stockholm, Sweden, on 14 July 1967, and was amended on 28 September 1979.

Today the administration of the Paris convention is governed by the WIPO who has its office in Geneva, Switzerland

As of September 2014, the Convention has 176 contracting member countries, which makes it one of the most widely adopted treaties worldwide. Notably, Taiwan and Burma are not parties to the Convention. However, according to Article 27 of its Patent Act, Taiwan recognizes priority claims from contracting members.

The Paris Convention applies to industrial property in the widest sense, including patents, trademarks, service marks, trade name, industrial designs, and utility models.

The substantive provisions of the Convention fall into three main categories: national treatment, right of priority, common rules.

(1) Under the provisions on **national treatment**, the Convention provides that, as regards the protection of industrial property, each Contracting State must grant the same protection to nationals of other Contracting States that it grants to its own nationals. Nationals of non-Contracting States are also entitled to national treatment under the Convention if they are domiciled or have a real and effective industrial or commercial establishment in a Contracting State.

(2) The Convention provides for the right of priority in the case of patents (and utility models where they exist), marks and industrial designs. This right means that, on the basis of a regular first application filed in one of the Contracting States, the applicant may, within a certain period of time, may apply for the patenet in the other state.

One of the great practical advantages of this provision is that applicants seeking protection in several countries are not required to present all of their applications at the same time but have 6 or 12 months to decide in which countries they wish to seek protection, and to organize with due care the steps necessary for securing protection.

(3) The Convention lays down a few common rules that all Contracting States must follow. The most important are:

(a) Patents. Patents granted in different Contracting States for the same invention are independent of each other: the granting of a patent in one Contracting State does not oblige other Contracting States to grant a patent; a patent cannot be refused, annulled or terminated in any Contracting State on the ground that it has been refused or annulled or has terminated in any other Contracting State.

The inventor has the right to be named as such in the patent.

The grant of a patent may not be refused, and a patent may not be invalidated, on the ground that the sale of the patented product, or of a product obtained by means of the patented process, is subject to restrictions or limitations resulting from the domestic law.

Each Contracting State that takes legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exclusive rights conferred by a patent may do so only under certain conditions. A compulsory license (a license not granted by the owner of the patent but by a public authority of the State concerned), based on failure to work or insufficient working of the patented invention, may only be granted pursuant to a request filed after three years from the grant of the patent or four years from the filing date of the patent application, and it must be refused if the patentee gives legitimate reasons to justify this inaction. Furthermore, forfeiture of a patent may not be provided for, except in cases where the grant of a compulsory license would not have been sufficient to prevent the abuse. In the latter case, proceedings for forfeiture of a patent may be instituted, but only after the expiration of two years from the grant of the first compulsory license.

(b) Marks. The Paris Convention does not regulate the conditions for the filing and registration of marks which are determined in each Contracting State by domestic law. Consequently, no application for the registration of a mark filed by a national of a Contracting State may be refused, nor may a registration be invalidated, on the ground that filing, registration or renewal has not been affected in the country of origin. The registration of a mark obtained in one Contracting State is independent of its possible registration in any other country, including the

country of origin; consequently, the lapse or annulment of the registration of a mark in one Contracting State will not affect the validity of the registration in other Contracting States.

Where a mark has been duly registered in the country of origin, it must, on request, be accepted for filing and protected in its original form in the other Contracting States. Nevertheless, registration may be refused in well-defined cases, such as where the mark would infringe the acquired rights of third parties; where it is devoid of distinctive character; where it is contrary to morality or public order; or where it is of such a nature as to be liable to deceive the public.

If, in any Contracting State, the use of a registered mark is compulsory, the registration cannot be canceled for non-use until after a reasonable period, and then only if the owner cannot justify this inaction.

Each Contracting State must refuse registration and prohibit the use of marks that constitute a reproduction, imitation or translation, liable to create confusion, of a mark used for identical and similar goods and considered by the competent authority of that State to be well known in that State and to already belong to a person entitled to the benefits of the Convention.

Each Contracting State must likewise refuse registration and prohibit the use of marks that consist of or contain, without authorization, armorial bearings, State emblems and official signs and hallmarks of Contracting States, provided they have been communicated through the International Bureau of WIPO. The same provisions apply to armorial bearings, flags, other emblems, abbreviations and names of certain intergovernmental organizations.

Collective marks must be granted protection.

(c) Industrial Designs. Industrial designs must be protected in each Contracting State, and protection may not be forfeited on the ground that articles incorporating the design are not manufactured in that State.

(d) Trade Names. Protection must be granted to trade names in each Contracting State without there being an obligation to file or register the names.

(e) Indications of Source. Measures must be taken by each Contracting State against direct or indirect use of a false indication of the source of goods or the identity of their producer, manufacturer or trader.

(f) Unfair competition. Each Contracting State must provide for effective protection against unfair competition.

The Paris Union, established by the Convention, has an Assembly and an Executive Committee. Every State that is a member of the Union and has adhered to at least the administrative and final provisions of the Stockholm Act (1967) is a member of the Assembly. The members of the Executive Committee are elected from among the members of the Union, except for Switzerland, which is a member ex officio. The establishment of the biennial program and budget of the WIPO Secretariat – as far as the Paris Union is concerned – is the task of its Assembly.

The Paris Convention, concluded in 1883, was revised at Brussels in 1900, at Washington in 1911, at The Hague in 1925, at London in 1934, at Lisbon in 1958 and at Stockholm in 1967, and was amended in 1979.

The Convention is open to all States. Instruments of ratification or accession must be deposited with the Director General of WIPO.[19]

3.2 Berne Conventions

The Berne Convention for the Protection of Artistic and Literary works is an international agreement governing copyright and first accepted in Berne, Switzerland, in 1886, which came into effect on 5 December 1887 and has 168 signatory parties to it currently.

United States joined the Convention March 1, 1989 after 102 year of coming into effect of this treaty and UK signed the treaty but it did no implemented its large part even after 100 years of its signatory and implemented it only after with the passage of the Copyright, Designs and Patents Act 1988.

[19] http://www.wipo.int/treaties/en/ip/paris/summary_paris.html

Since almost all nations are members of the World Trade Organization, the Agreement on Trade-Related Aspects of Intellectual Property Rights requires non-members to accept almost all of the conditions of the Berne Convention.

Berne Convention was influenced by the French "right of the author", which only dealt with economic concerns. Under the Convention, copyrights for creative works are automatically in force upon their creation without being asserted or declared. An author needs not to register himself or apply for a copyright in countries which is party to the Convention. As soon as a work is fixed, that is, recorded or written on some physical medium and its author is automatically entitled for the copyrights in the work and to any derivative works, unless and until the author explicitly sale them, transfer them or until the copyright expires. Foreign authors are given the same rights and privileges to copyrighted material as domestic authors in any country that signed this Convention. Before the Berne Convention, national copyright laws usually only applied for works created within each country. Example a work published in United Kingdom by a British national would be covered by copyright there, but could be copied and sold by anyone in France. The Berne Convention followed in the footsteps of the Paris Convention for the Protection of Industrial Property of 1883, which in the same way had created a framework for international integration of the other types of intellectual property: patents, trademarks and industrial designs. Like the Paris Convention, the Berne Convention set up a bureau to handle administrative tasks. In 1893 these two small bureaux merged and became the United International Bureaux for the Protection of Intellectual Property (best known by its French acronym BIRPI), situated in Berne. In 1960, BIRPI moved to Geneva, to be closer to the United Nations and other international organizations in that city. In 1967 it became the World Intellectual Property Organization (WIPO), and in 1974 became an organization within the United Nations. The Berne Convention was revised in Paris in 1896 and in Berlin in 1908, completed in Berne in 1914, revised in Rome in 1928, in Brussels in 1948, in Stockholm in 1967 and in Paris in 1971, and was amended in 1979. The World Intellectual Property Organization Copyright Treaty was adopted in 1996 to address the issues raised by information technology

Today Bern convention work WIPO and has most numbers of signatory than any other treaty protecting the right of copyright holders at global level currently it has 168 members whereas UN has 167 members.

3.3 WIPO (world intellectual property organization)

WORLD INTERNATIONAL PROPERTY ORGANIZATION formed to promote the protection of patents, trademarks, and designs and copyright. WIPO was created in 1967 "to encourage creative activity, to promote the protection of intellectual property throughout the, it began its operations in 1970 and became a specialized agency of the United Nations in December 1974 world it's one of the 17 specialized agencies of the UN.

WIPO was formally created by the Convention Establishing the World Intellectual Property Organization and currently has 188 member states, administers 26 international treaties and is headquartered in Geneva, Switzerland.

The **origins of WIPO** can be traced to 1883, when 14 countries signed the Paris Convention for the Protection of Industrial Property, which created intellectual-property protections for inventions, trademarks, and industrial designs. The convention helped inventors gain protection for their works outside their native countries. In 1886 the Berne Convention required member countries to provide automatic protection for works that were produced in other member countries. The two organizations, which had established separate secretariats to enforce their respective treaties, merged in 1893 to become the United International Bureau for the Protection of Intellectual Property (BIRPI), which was based in Bern, Switzerland.

In 1960 BIRPI moved its headquarters to Geneva. The aims of WIPO are twofold. First, through international cooperation, WIPO promotes the protection of intellectual property. The organization now administers more than 20 intellectual-property treaties. Second, WIPO supervises administrative cooperation between the Paris, Berne, and other intellectual unions regarding agreements on trademarks, patents, and the protection of artistic and literary works. WIPO's role in enforcing intellectual-property protections increased in the mid-1990s, when it signed a cooperation agreement with the World Trade Organization. As electronic commerce grew through the development of the Internet, WIPO was charged with helping to resolve disputes over the use of Internet domain names.

WIPO's membership consists of more than 180 countries. Its main policy-making body is the General Assembly, which convenes every two years. WIPO also holds a biennial conference, which determines the organization's budget and programs. More than 170 non-governmental organizations maintain observer status. [20]

Between 1996 and 2000, WIPO gave legislative advice to 119 developing countries and regional organizations in the form of 214 draft IP laws, and comments and other advice.

Article 3 of the **Stockholm convention on July 14, 1967** which formed the basic guideline for the formation of the WIPO define the objectives of the organization Article 3(1) and 3(2) talks about:

1) To promote the protection of intellectual property throughout the world through cooperation among States and, where appropriate, in collaboration with any other international organization,
2) Ensure administrative cooperation among the Unions. [21]

It defines the corporation of the states in terms of Protecting the IP and laid the foundation for the compulsory licensing by cooperation between the nations and organizations.

WIPO drafted several IP laws and provided advice to the nations, organization and fees based service to private companies it also have emerged as the alternate dispute center for resolving dispute.

After 1994 WTO underwent a joint cooperation project with WIPO to underway to protect and analysis the extent of essential medicine in the developing and underdeveloped countries.

The WIPO submitted reports on its Technical and financial assistance activities to the TRIPS council. The idea of promoting the flexibility in the TRIPS is not expressed until 2005.

In 2005, the submission shows and reports a shift in focus in the WIPO activities. Two priority areas are listed: a) assisting countries in creating IP assets and realize real benefits from these assets and b) providing legal and general advice on using flexibilities in TRIPS and WIPO

[20] http://www.britannica.com
[21] Convention Establishing the World Intellectual Property Organization 1967

treaties, through which countries may promote national goals of economic and social developments. In 2006, there is the first specific mentioning of providing assistance for implementing the Decision. WIPO initiates a study on the nature, extent and implementation of flexibilities available under the Paris convention and the TRIPS as regards the protection of inventions in the pharmaceutical sector. Workshops and forums are held on the topic of IP and public health.[22]

The TRIPS flexibilities are currently emphasized on WIPO website also saying that development objectives. But there is nowhere mention about the assistance of WIPO to TRIPS, Certainly, the assistance may promote flexibilities without explicitly saying so, or conversely not promote them despite saying so. These sources can only give an indication of what WIPO considers important to mention. As its legislative advice is provided on a confidential basis to the country concerned, it is difficult to ascertain how the flexibilities are treated.

The principles for technical assistance have recently been addressed within the "Development Agenda", adopted by the WIPO General Assembly on 28 September 2007. The purpose is to make WIPO more development-conducive. The TFA related proposals say inter alia that the WIPO shall "make available advice to developing countries and LDCs, on the implementation and operation of the rights and obligations, and the understanding and use of flexibilities contained in the TRIPS Agreement".

WIPO's advice focused on ensuring that national legislation would be in compliance with those obligations. Since 2000, and in particular since the beginning of TRIPS, WIPO is providing the assistance to the country who are party to the trips agreement and working towards the implementation of guidelines provided in the TRPS agreement WIPO is also acting as an ADR mechanism for resolving the dispute between the parties to the agreement.

3.4 TRIPS AGREEMENT

[22] The WTO Decision on Compulsory Licensing, Kommers Kollegium, 2002.

The WTO, in December 1994, approved an important treaty the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) which came into effect on January 1, 1995. Primary objective of TRIPS Agreement was to minimize the distortions and impediments to global trade by giving due importance to protection of IPRs (Arnold, 1993). It provided for minimum standards to harmonize divergent domestic laws of the WTO member countries and provided mandatory rights for right holders. It required all WTO member states to adopt regulations relating to IPRs as laid down in the treaty.

TRIPS Agreement did not repeal Paris Convention. Rather it incorporated Paris Convention under its Article 2(1) and both apply on equal footing. TRIPS, however, provided for higher standards of intellectual property protection and it is difficult to reconcile Article 27(1)[23] of TRIPS with Article 5(A) of the Paris Convention. The TRIPS Agreement, under Article 27(1), provides that the signatory states are obliged to protect any innovations, whether products or processes, in all fields of technology.

Before 1995, when TRIPS Agreement was not concluded, almost 50 countries had excluded drugs from patentability .But TRIPS Agreement prohibited any such exclusion. To enjoy protection, the invention must fulfill three conditions namely, "it must be new, it involves an inventive step, and it is capable of industrial application". Moreover, TRIPS Agreement, under Article 28, provides the patent holders exclusive rights to prevent third parties from making, using, offering for sale, selling or importing patented products without consent of the patent holder.[24]

These monopoly rights are provided to the patent holders for a period of twenty years. The pharmaceutical patent protection, however, works well only in high income countries with citizens having purchasing power to buy expensive patented pharmaceuticals. It does not work well in developing and least developed countries because of different factors, affordable access to medicines being the most important of them.

[23] Article 27(1) stipulates that: "…patents [can] be granted for any invention, whether products or processes, in all fields of technology..[and] patent rights enjoyable without discriminations to the place of invention, the fieldof technology and whether products are imported or locally produced"
[24] TRIPS Agreement, Article 28(1)(a).

TRIPs never mention the about "compulsory license" in it. Yet, Article 31 describes an allowable exception to patent enforce-ment in language implying compulsory licensing; exception laid down form the basis of compulsory licensing in the trips

Keeping in view the practical implications of patent protection in third world countries, TRIPS Agreement provides mechanisms to poorer countries to override patents through legitimate means. It contains arrangements such as 'parallel importation' and 'compulsory licensing' which are exceptions to the stringent patent protection. Even though the word 'compulsory license' has never been used in the TRIPS Agreement, the exclusive rights to the owner of patents are specifically subject to compulsory licensing under the Agreement. Article 30 of the TRIPS Agreement provides:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Under Article 31, TRIPS Agreement provides an exception to the monopoly rights of patent owners. Instead of listing or defining situations in which compulsory license may be granted, it only sets out certain conditions for the issuance of non-voluntary license. Leaving the matter to the signatory states, TRIPS Agreement imposes safeguards to avoid abuse of rights. The specific terms therefore vary from country to country. The signatory states decide each case of granting a compulsory license on case-by-case basis. It would be against the essence and spirit of Article 31 of **TRIPS Agreement if a person becomes legally entitled to get a compulsory license automatically upon fulfillment of certain conditions.**

There is a condition that proposed user must have made reasonable commercial efforts to negotiate with the owner of the patent for permission to use the patent for a reasonable period of time (TRIP Agreement, Article 31(b). However, this condition of prior negotiation with the owner of the patent may be dispensed with in the cases of national emergency, or situations of extreme urgency, or for public non-commercial use.

The TRIPS Agreement makes a provision that the owner of the patent must be provided an adequate royalty as a matter of right (TRIP Agreement, Article 31(h)). Remuneration is decided on the case-by-case basis depending on the economic value of the authorization. In order to

determine whether or not any decision of granting a compulsory license was legally valid and to provide an opportunity to the patent owner to prevent abuse of his right, TRIPS Agreement obliges the signatory states to a judicial review or other independent review (TRIP Agreement, Article 31(i). The reviewing authority must be a higher one having the power to reverse, vary or annul the original decision of the license granting authority.

There is also a provision in the TRIPS Agreement which allows compulsory license in the case of dependent patents. "A dependent patent is one that can be used only after infringing an earlier existing patent." Consequently, both parties cannot make effective use of the innovation; invention of the second party violates patent of the first party and first party is also barred from using the second party's improved innovation. Therefore the improved invention would not be used if the parties fail to reach a licensing agreement. As a result, the community would not be able to reap the fruits of the innovation. Compulsory licensing provisions may be invoked to force the parties to either allow use of the patent after receiving remuneration agreed upon between the parties or cross-license their patents to ensure working of the patent.

It must be noted that an extended period of time was granted to the developing and least developed countries to conform to TRIPS Agreement. An extended period up to January 1, 2000 was given to developing countries during which they were not required to conform to most of the provisions of the TRIPS Agreement. The least developed countries were given an initial transition period up to January 1, 2006. In November 2005, however, the WTO member countries agreed on further extension until July 1, 2013, or to date an underprivileged state is no longer included in the category of least developed countries, if that occurs before the end of the deadline. A further extension in the deadline until January 1, 2016 was given to the least developed countries by the TRIPS member nations. This, however, remains a fact that the least developed countries despite being lawfully allowed to manufacture generics until 2016 cannot do it realistically owing to the fact that they have no manufacturing capacity.

However, for pharmaceuticals and agricultural chemicals, the TRIPS member nations that were yet to provide patent protection on January 1, 1995 were under two obligations. Firstly, these countries were under an obligation to receive patent applications from inventors from January 1, 1995; they could, however, delay their decision to grant or not to grant patent until the end of the extended period. The aforementioned obligation is under article 70, paragraph 8 of the TRIPS

Agreement which is also called 'mailbox' provision because it allows states to receive and store the applications. Secondly, if state allowed marketing of such products during the extended period, the state was under an obligation to provide exclusive marketing rights to the patent applicant for five years, or until a judgment was made on the application for the grant of patent.

This obligation was, however, subject to certain conditions. This provision is found in Article 70, paragraph 9 of the TRIPS Agreement. Article 31(f) of the TRIPS Agreement puts an important limitation on the use of involuntary license. Article 31(f) of the TRIPS Agreement stipulates that "any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use" (TRIP Agreement, Article 31(f). A narrow interpretation of this provision suggests that non-voluntary license can be used only for consumption of the product within the country. It cannot be used for export of the product manufactured under compulsory license.

As a consequence, the access to essential life-saving medications may remain an unattainable dream in the countries which lack pharmaceutical manufacturing capacity or ability to reverse engineer the needed pharmaceutical product.

This provision has a twofold effect on developing and least developed countries. Firstly, the countries having insufficient or no manufacturing capacity cannot import drugs from countries that produce and export generic drugs, thus, denying availability of essential pharmaceuticals to their masses. Secondly, this restriction of the domestic market restricts the flexibility of developing countries which have the capacity to manufacture drugs to boost their economy by authorizing the export of compulsory licensed drugs. If a developing nation with enhanced technology such as India, Brazil, South Africa and the like has invoked compulsory licensing and is able to produce generic drugs, it still cannot supply the compulsory licensed drugs to other countries because of the domestic market limit provided in the Article 31(f).

Practically, in most of the developed countries, general compulsory licensing provisions are rarely invoked. According to a study conducted a decade ago, Switzerland has never invoked compulsory licensing provisions; Japan has invoked eight times since 1960;

France invoked three times since 1953, Canada invoked general (non-pharmaceutical) compulsory licensing provisions eleven times since 1935. Compulsory licenses are granted more

frequently in countries which in their national laws provide for special compulsory licensing provisions for pharmaceutical and food patents. Even where compulsory licensing provisions are rarely or never used, it is reasonable to assume that the presence of such provisions has significance in the patent system. Owing to the threat of compulsory licensing, patent owners negotiate licenses that they would otherwise refuse to negotiate.

Doha Declaration on TRIPS Agreement and Public Health

Discussion relating to public health was initiated in the TRIPS Council by African Group; many other developing countries facing similar problems also joined the discussion and supported African Group. Advanced countries had a difference of opinion with the third world countries. Based on the discussion, two different drafts were prepared; one draft was submitted by the U.S, Canada, Switzerland and some other advanced countries; another draft was submitted by the third world countries. The draft submitted by developing countries was adopted as Declaration on TRIPS Agreement and Public Health, with some amendments, during the fourth Ministerial Conference (a meeting of the world's trade ministers) of the WTO in Doha, Qatar in November 2001 in order to deal with the issues of public health, especially the issues rest luting from epidemics like tuberculosis,[25] malaria and the like and the global concerns like HIV. The members agreed that TRIPS should permit WTO member countries to take measures to protect the health of their.

The Doha Ministerial Declaration, a statement of intent , recognized a collective obligation to improve access to drugs for all and affirmed the right of nations to use the safeguards provided under TRIPS to meet public health concerns. It declared that each member has not only the right to grant compulsory license but also to determine grounds for the grantor license and to determine what constitutes national emergency Moreover, it stated that public health crisis can represent a national emergency. Paragraph 6 of the Declaration expressly acknowledged the issue faced by the WTO member countries having no capacity to manufacture generic drugs due to the restrictions put by Article 31(f) of the TRIPS Agreement. Doha Declaration allowed member nations to take possible steps to protect public health including import of the needed

[25] Paragraph 1 of the Doha Declaration mentions HIV/AIDS, tuberculosis, and malaria. However, it is argued that Paragraph 1 of the Doha Declaration should be interpreted broadly and generously to cover other important diseases.

drugs from other countries that had the ability and willingness to help if patent holders of pharmaceutical products had no objection. The Declaration, under Paragraph 7, also extended transition period for least-developed countries to January 1, 2016.

Taken together, although the purpose or intention of the Doha Ministerial Declaration was not to amend the TRIPS Agreement in any considerable manner (Correa, 2004) but to clarify and interpret what was already stipulated in the TRIPS Agreement, it was a victory of the developing world against the advanced world and the research-based brand-named pharmaceutical industry. Poorer countries won important concessions through persuasive moral arguments of third world leaders and AIDS activists, bargaining tactics, and effective strategic focus. Anthrax scare of 2001 also contributed to some extent in achieving greater latitude on non-voluntary licensing because the U.S –one of the staunch opponents of compulsory licensing- considered breaking patent of Bayer and used threat of compulsory license as a means of negotiating a lower price for Capri, an anthrax antidote.

The waiver, however, is not absolute. It can be used to the extent necessary and subject to certain conditions. The state intending to use this waiver must be an eligible importing country i.e. either least developed or a developing country with insufficient drug manufacturing capacity. Moreover, the eligible importing country must give a general notification (Annex to the Protocol Amending The Trip Agreement, Article 31 of intent to use the mechanism to the Council for TRIPS along with information like name and expected quantity (Article 31 bis, 2(a) (i)) of the product needed and a confirmation (Article 31 bis, 2(a) (ii)) that the country lacks manufacturing capacity (Abbott, 2005). The Council will review the notification before giving approval. In cases of an outbreak of an epidemic, this condition may cause delay in the availability of the required drug.

Furthermore, the quantity of drugs that can be manufactured for export under a non-voluntary license is subject to restrictions and can only be exported to the country lacking manufacturing capacity and facing public health crisis. There is a further condition on the country wishing to export compulsory licensed drugs that it would do so on a "non-commercial basis".

Similarly, the exporting country shall also notify the "Council for TRIPS" of the issuance of the compulsory license along with some information like the product for which compulsory license

has been issued, name and address of the licensee , the quantity of the produce, duration of the compulsory license, and the country to which the product is to be supplied. The exporting licensee is also required to provide the aforementioned information on a website (Article 31 bis, 2(b) (iii)).

In order to prevent trade diversion or misuse of the Waiver, the products manufactured shall be distinguished rather clearly identified from the generics which are manufactured for domestic use. The distinction can be made through distinguishable packaging or coloring or special color or shape of the product itself to distinguish it from other products in the normal supply chain. The exporting member is required to maintain a meticulous account of pharmaceuticals prepared under the compulsory license and the importing member is required to take all possible measures to make sure that the pharmaceuticals manufactured under compulsory license are not re-exported. Re-export is, however, allowed among members of a regional trade agreement.

This interim Waiver -subject to the aforementioned conditions for both the importing and the exporting countries- was adopted as a temporary solution until the amendment of TRIPS Agreement and tried to address the initial problem caused by Article 31(f). It was heralded as a success because it addressed a grave concern of the third world countries having no manufacturing capacity of their own. It, however, seems to have created more hurdles because the procedure involves bureaucratic obstacles for third world countries that want to avail the exemption. Though the mechanism is to provide prompt solution to emergency situations of public health crisis, numerous procedural requirements to ensure that the flexibility is not abused and to avoid trade diversions make the mechanism costly and unnecessarily burdensome. The system can be made to work through political determination, coordinated planning, and skillful lawyering which third world countries normally lack.

Article 31bis: An Amendment to the TRIPS Agreement (Hongknong Convention 2005)

On December 6, 2005, shortly before Hong Kong Ministerial Conference, the WTO member states agreed to amend the TRIPS Agreement to incorporate the WTO General Council's waiver decision as a permanent part of the TRIPS Agreement. The aforementioned Doha Paragraph 6 implementation agreement was submitted to the WTO and was adopted as Article 31 bis in December 2005. The 6 December 2005 amendment in the TRIPS Agreement is based on the

WTO General Council's Waiver Decision. Although the wording of the amendment is different, it contains almost the same elements as the Decision. Five paragraphs of Article 31bis are compatible with the text of paragraph 2, 3, 6, 9 and 10 of the Waiver Decision; the purpose of this amendment was to address the limitations and confusion surrounding Article 31(f) of the TRIPS Agreement. This amendment embodies a compromise because no stakeholder was able to achieve all of its objectives.

To use this mechanism, the WTO member states need to amend their national laws to permit issuance of these special licenses. For poor countries, this seems a difficult task to undertake in view of strong pharmaceutical lobby. Article 31bis still leaves some ambiguities, for instance, it does not state formula for determining adequate remuneration.

This issue of remuneration will trigger debate and even litigation whenever a country attempts to use the mechanism. Moreover, unnecessary administrative hurdles make Article 31bis a less effective provision for third world countries. It does not provide administratively simple, straightforward and expeditious solution to the problem. An administratively complex, expensive and time-consuming regime involving back-to-back compulsory licenses was adopted because the United States and the European Union rejected the simple and straightforward solution suggested by the developing countries.

The oral statement made by the WTO General Council Chairperson put further limits on the use of this mechanism. According to this statement the flexibility could be used only in circumstances of extreme urgency and not as "an instrument to pursue industrial or commercial policy objectives". The legal status of the statement made by the WTO General Council Chairperson is not clear as these words are not used in text of the amendment. It makes the Waiver more ambiguous and complex.

The provision had to be ratified by two thirds of WTO members, but it witnessed lukewarm international response not only from developed countries but also from developing and least-developed countries. The developed countries were primarily against this flexibility that was against the interests of their pharmaceutical industry, but they had to agree because the negotiations between interested stakeholders failed to find any other mutually agreed solution. They had serious reservations that the flexibility would be abused by the third world countries

and it would promote a culture of disrespect for IPRs. Their reluctance to ratify the provision reflected the same. The poorer countries also hesitated to ratify the amendment owing to lobbying and pressure of advanced countries and multi-national pharmaceutical companies.

It is pertinent to note that though TRIPS provided the flexibility and Doha Declaration 2001, Waiver Decision 2003, and 2005 Amendment reaffirm WTO member country's right to issue compulsory license, the flexibility has been rarely used by the poorer countries owing to numerous factors. Though the WTO General Council's Waiver Decision provided interim solution in 2003 that was made part of TRIPS in 2005, not even a single country tried rather dared to invoke this mechanism.

Despite of WTO's hard efforts to create a diplomatic compulsory licensing system that improve use of prescription medicine, there are lack of some specific requirement. The factor which bar poorer countries from availing the flexibility include fear of economic consequences in the form of loss of foreign direct investment, countervailing pressures by pharmaceutical industry and governments of powerful states, fear of trade sanctions, reactions and retaliations of developed countries, lack of technical expertise, high costs of patent litigation, bilateral and regional TRIPS-Plus free trade agreements, and various other factors. A detailed discussion on these factors is beyond the scope of this work, but it has been observed that the ability to use compulsory license greatly depends on economic and political strength of a country.

4 NEXUS BETWEEN COMPULSORY LICENSING AND COMPETITION LAW

Competition law promotes or seeks to maintain market by regulating anti-competitive conduct by companies in the market. Competition is not defined is not defined anywhere but is generally understood to mean the process of rivalry to attract more customers or enhance profit by way of some illegal mean.

The history of competition law can be traced back to the enactment of Sherman Act in 1890 in the USA. This act was directed for the predations and power of the trusts formed in the wake of the Industrial Revolution where a small control group acquired and held the stock of competitors, usually in asset, and controlled their business. Gradually, competition law came to be recognized as one of the key pillars of a market economy. This recognition led to enactment of competition law in many countries, including developing countries, and the number now stands at around 105.

In India the Competition Act, 2002 was passed by the Parliament in the year 2002, to which the President accorded assent in January, 2003. It was subsequently amended by the Competition (Amendment) Act, 2007.

In accordance with the provisions of the Amendment Act, the Competition Commission of India and the Competition Appellate Tribunal have been established. The Competition Commission of India is now fully functional with a Chairperson and six members. The provisions of the Competition Act relating to anti-competitive agreements and abuse of dominant position were notified on May 20, 2009.

Whereas competition law in UK can be traced from 12th century, Modern competition law UK is heavily relied upon by the American experience. The so-called Sherman Act of 1890 and the Clayton Act of 1914 followed by Monopolies and Mergers Act 1965 and the Monopolies and Restrictive Trade Practices Act 1969 which was bought to control the private industries to form cartel.

In 1972 UK joined European Union with the European Community Act 1972 and became subject to EU competition law. Where any UK company is subject to anti-competition act it will be dealt with EU anti-competition laws and EU laws will be allowed.

Competition in the market means competing for quality of product, pricing and resources, leading to a market oriented towards consumer's right, fair trade, and efficient allocation of resource, small businesses development, incentives for innovation and dispersion of economic power

Compulsory licenses are generally defined as "authorizations permitting a third party to make, use, or sell a patented invention without the patent owner's consent." Under Indian Patent Act, 1970, the provision with regard to CL is given under Chapter XVI. Internationally also, the provision of compulsory licensing is well-recognized be it US or UK already been discussed above. The inbuilt flexibility provided under TRIPS agreement also paved the way to grant of compulsory licensing. This is done while keeping the interest of public at large.

Since compulsory licensing limits the right of exclusive ownership conferred by patents, copyright, it was also controversial. When it comes to implementation of compulsory licensing, there has been little consensus among the countries who are signatories of TRIPS, developed countries generally tend to view this provision with suspicion, while the developing countries consider it as an issue of prime importance.

The application and enforcement of competition law to IPR is highly topical & hotly debated. The reason for the debate is that while IP laws, confer exclusive rights (patent act), while competition law seeks to ensure a competitive market place. The monopoly granted to a holder of an IPR can create barriers or restriction to entry and give rise to market power and the abuse of which is prohibited by competition law. As a result, some courts, academics and practitioners see an inherent conflict between these two bodies of law and have traditionally sought to balance the need for incentivizing innovation through exclusivity protection with the efficiency benefits of open access competition.

Whilst IP laws grant exclusivity and, in doing so, may inhibit competition, both IP and competition law share the common aim to encourage innovation, enhancing consumer welfare and encouraging efficiency. Academician on the subject has recognised IP and competition law as being re-enforcing and mutually complementary. [26]

Moreover, competition law does not seek to prohibit exclusivity per se; it aims to prevent the misuse or abuse of exclusivity in certain circumstances. This is evidenced by the prohibition of exclusivity agreements only where enterprises in a vertical relationship enjoy market power or where exclusivity arrangements are imposed by a dominant enterprise.

[26] http://www.cci.gov.in accessed on 27/3/2105

In anti-trust violations also the compulsory licensing may be resorted to as a remedy where patent has been abused or where the protected product is vital to national interest or the licensee getting the compulsory license is the government. Therefore, there are situations where the interest of society at large should be given more importance than the personal rights in the form of IPRs.

The interface between IPRs and Competition law is a very delicate and complicated. The IPRs prohibit imitation and copying of products, product characteristics, industrial designs etc. and in a way they also contribute to fair competition in market. On the other hand the competition law may restrict the exclusivity provided by IPR if the exclusivity has been exploited to exclude others from business by anti-competitive means. Therefore, a too high or too low protection of both the IPRs and competition may prove bad for market as it will unnecessarily create distortions in the trade. An optimum level of protection to both IPR and competition law is thus, desirable for promotion of competition in markets. Many countries like Ecuador, South Africa, Kenya, Tanzania, Malaysia and Thailand have resorted to compulsory licensing of HIV drugs and the effect of compulsory licensing has been incredible.[27]

The ideal situation in which consumer welfare is maximized is perfect competition. The concept of perfect competition calls for a situation wherein all the producers are manufacturing undifferentiated product and the price they charge for their product is the same. In perfect competition there is no incentive for innovation as advantage acquired by the means of innovation evaporates in the absence of intellectual property rights. Thus, the argument that competition abhors protection holds its ground at least theoretically.[28]

In practical world the interface of IPR and competition has been uncertain to a great extent, where results have differed drastically in different products. Patents in technological innovations have resulted in to a more competitive market in car manufacturing, satellite communication and telecom markets. Whereas in drugs, seeds and software markets the IPRs have given rise to fewer competitors and less competitive markets.

[27] http://www.avert.org/generic.htm, Accessed on 28 march 2015.
[28] http://www.cci.gov.in accessed on 27/3/2105

There are few examples wherein innovation has led to windfall of revenue to companies without them being patented or patented in a very weak patent regime. If we look at the technologies that are at the heart of Information and communication technology we come to know that even compulsory licensing of transistor could not stop Bells Labs to harvest handsome revenue that laid foundation of semiconductor industry.[29] Semiconductor industry as well as software industry emerged under a weak IP regime. The telecom industry was also controlled by national monopolies until 1990s across the globe and it developed to the great extent without being protected under IPRs. Therefore, the argument that exclusive rights in the form of IPRs are the only way to promote innovation is not true every time.

Exclusive rights protected in the form of IPRs do create a situation wherein other parties who are capable and willing to produce the product are stopped from doing so. There is a fair number of instances wherein IPR protected monopoly has been abused to curb competition. Following instances may be called as abusive use of Intellectual property rights.

1. Patent Pooling wherein two or more companies come together and cross license the technology relating to a particular technology to each other so as to restrict others to acquire it.

2. Tie in arrangements to tie a product with other product which is patented so that the acquirer has to get the other product also from the patentee.

3. Royalty Payment after expiry of patent.

4. Prohibiting licensee to use technology from rival company.

5. Prohibiting licensee from challenging validity of IPR.

6. Price-fixation for the licensee to sell the licensed product. Generally the older cases involving antitrust and intellectual property were related to patent misuse whereas the newer ones relate to copyright misuse. Patent misuse is a judge made doctrine wherein the patent stands forfeited if the patent holder uses that patent in an improper way. Tying arrangements, in which a party

[29] Giovanni Dosi, Luigi Marengo, Corrado Pasquali and Marco Valente, Knowledge, competition and appropriability: Is strong IPR protection always needed for more and better innovations? Accessed at https://mail.sssup.it/~l.marengo/marengo.pdf on march 28 2015.

agrees "to sell one product but[30] only on the condition that the buyer also purchases a different product, or at least agrees that he will not purchase that product from any other supplier, have also been held as anticompetitive and in violation of antitrust laws in various jurisdictions. The most famous case on this issue has been the recent case of United States v. Microsoft[31]. In this case the case was brought by 20 states and United States Department of Justice against the Microsoft Company under Section 113and Section 214 of the Sherman Act of 1890. The Federal Circuit Court of Appeals of District Columbia in this case held that the Microsoft's dominance in the field of Intel based Operating Systems constituted a monopoly. Further the court reasoned that there was abuse of monopoly by Microsoft because of bundling of Internet Explorer web browser and windows operating System. It gave unfair leverage to Microsoft against other competitors in web browsing industry.

Netscape Navigator and Opera were restricted by the abuse of monopoly based on IP by Microsoft in this case. Microsoft had altered and manipulated and altered its application programming interfaces to allow only Internet Explorer to run on Windows Operating System. Windows operating systems was a product that was Intellectual Property of Microsoft15 and protected under Patent Act but the way in which it tied up Internet Explorer to it was held as anti-competitive and Microsoft was held guilty of illegal restraint of trade and monopolization of trade.[32]

This is a classic example of how a company holding an exclusive right under IPRs can abuse its exclusivity to get unethical and illegal leverage. In Indian Competition Act 2002 also such tie in agreements are held as anti-competitive under Section 3 (4) a. Such tie in agreements are very much prone in the products wherein the main product is protected by patent and has considerable market capitalization and the tying product has its substitutes in market but the illegal extension of patent protected monopoly restricts the consumers to use the substitutes of the tying product, this was exactly the case in Microsoft case and it was held as illegal and Microsoft was compelled to come to a settlement with other rivals in web browser industry. This is a seminal

[30] William M. Landes, Richard A. Posner, The economic structure of intellectual property Law, The Belknap Press of Harvard University Press, Massachusets, 2003, p. 372.
[31] CA No. 98-1232 (CKK)
[32] Case 24/67 Parke Davis v Probel, [1968] ECR 81

case of abuse of IPR by bundling the other product in a way to lead the market share in monopolistic way by resorting to unfair trade practices.

A lot of countries have issued compulsory licenses for anti-competitive misuse of IPRs by companies. According to a survey around 53 countries in the world have given compulsory licenses after the comeuppance of TRIPS agreement. Brazil, Thailand, Malaysia, South Africa, Kenya, Ecuador etc. have issued compulsory licenses over the patent rights of AIDS drugs and recently India has joined the bandwagon of compulsory licensing when the Patent Controller awarded compulsory license on a cancer drug Nexavar patented by Bayer to generic drug maker Natco Pharma. Indian Patent Act has provisioned for compulsory licensing since its enactment in 1961.

Compulsory licensing of IPRs in India has raised a lot of eye brows as the Indian pharmaceutical industry is third largest pharmaceutical industry in the world second only to United States and Japan. There is great a number of pharmaceutical companies in India and most of them are producing generic drugs. The compulsory licensing order has been passed recently this year so the effect of compulsory licensing of IPRs has yet to be felt practically in India Competition Act 2002

4.1 SCENARIO IN INDIA

After the repealed of the MRTP Act competition commission for formed under the Competition commission act 2002 which look in to the matter of anti-competition, monopoly related issues.

The various provisions of the Act deals with the establishment, powers, functions as well as discharge of the adjudicatory functions by the Commission. Under the scheme of the Act, this Commission is vested with inquisitorial, regulatory, investigative, and adjudicatory and to a limited extent towards advisory jurisdiction.

While keeping in view the nature of controversies arising under the provisions of the Act and public interest at large, the matters should be taken to the logical end of pronouncement of final orders without any undue delay. In the event of delay, the very purpose and object of the Act is

likely to be frustrated and the possibility of great damage to the open market and resultantly, country's economy cannot be ruled out.

Three main elements which are intended to be controlled by implementation of the provisions of the Act, which have been specifically dealt under Sections 3, 4 and 6 read with Sections 19 and 26 - 29 of the Act. They are abuse of dominant position, anti-competitive agreements and regulation of combinations which are likely to have an adverse effect on competition.[33]

The Competition Act 2002 does not permit any unreasonable condition forming a part of protection or exploitation of intellectual property rights. According to the section 3(5) nothing in the Section 3 shall restrict the right of any person to restrain any infringement of, or to impose reasonable conditions, as may be necessary for protecting any of his rights which have been or may be conferred upon him by IP laws. In other words, licensing arrangements likely to affect adversely the prices, quantities, quality or varieties of goods and services will fall within the contours of competition law as long as they are not in reasonable juxtaposition with the bundle of rights that go with IPRs. Therefore the reasonability of the conditions in agreements involving IPRs has to be there to avail the exception under Section 3 (5) of Indian Competition Act or otherwise CCI may be called upon to take note of anti-competitive agreement under Section 19 of the Act and it may pass order of divesture of intellectual property or compulsory licensing under the provisions of the Act.

The disagreement between the IPRs and competition law was encountered in a few cases before MRTP Commission. Section 15 of MRTP Act excluded the application of provisions of the Act to patented products similar to that of Section 3(5) of the Competition Act. In Vallal Peruman v. Godfrey Philips (India) Limited the Commission observed that the provisions of the Monopolies and Restrictive Trade Practices Act would be attracted only when there is an abuse in exercise of the right protected. This principle was again reiterated in Manju Bhardwaj case where the matter was related to manipulation, distortion, contrivances and embellishments etc by way of misuse of trademarks. Thus, it can be safely deduced that even before the enactment of Competition Act 2002 the unfair trade practices emanating from misuse of IPRs were coming under the ambit of MRTP Act and similarly similar issues can be undertaken by CCI under the mandate of

[33] Srishti Dutt, CCI, COMPETITION LAW IN INDIA, US & UK: A COMPARITIVE ANALYSIS, 2012

Competition Act 2002. In another case Mahyco-Monsanto Biotech India Limited was also indicted by MRTP Commission of unfair trade practices as it was abusing its dominant position by charging high royalty fee which made the seed exorbitantly costly to the farmers. These cases consolidate the arguments that the monopoly acquired by IPRs is prone to abuse by IPR holder and in many cases the dominant position protected by IPRs has been used to curb competition by many companies.

Indian economy being developing economy is witnessing healthy competition in every field, fair competition and protection of anti-competition always has been the mechanism for protecting economic efficiency in India. IP laws provide an exclusive monopoly rights to the owner of IP who has given his labour to develop it, whereas competition law deals with the prevention of monopoly and promotes healthy competition in the local market and preventing anti-competitive business practice. Hence there is a debate creating conflict between both the laws.

Competition laws are also framed with the intention of curbing abuse of market power by a dominant company and to protect the interest of the society at large.

Compulsory licenses are generally defined as "The Person not being the owner of the patent can claim for the licensing of the patent after 3years from the grant of patent or after 4 years from application for grant of such patent. The provision with regard to compulsory licensing is given under Chapter XVI 1 specifically. Internationally TRIPs agreement lays down the provisions related to grant of compulsory licensing and its implementation in the nations IP Laws, Member of TRIPs, WIPO are bound to follow the policies of compulsory licensing.

Competition law in India is based on restoring effective competition in the market place where as compulsory licensing is granted on considering the public interest at large. IP and competition law are not opposite instead they share a common objective which may promote static efficiency and create a favorable environment enhancing consumer welfare and encouraging innovation.

ANALYSING BAYER CORPORATION V. NATCO PHARMA LTD.

Bayer was granted the patent for life saving cancer drug in India in 2008. Natco, an Indian pharmaceutical company, had applied to Bayer for a voluntary licence to manufacture and sell the drug, and proposed to sell sorafenib tosylate at a price of Rs 8,800 for a month’s therapy in

2010. However, Natco‟s request was refused by Bayer. Thereafter Natco filed an application before the Controller general of Patent. Three years after the grant of Bayer‟s patent, Natco filed an application for the grant of a compulsory license at the Indian Patents Office invoking the Sec. 84 which lays down the condition for the grant of compulsory licensing in India. Controller General of Patents of Indian Patents Office concluded that all the grounds provided in the Sec. 84 for the grant of compulsory licensing have been satisfied and granted the compulsory licensing to Natco Pharma with 6% royalty.

Bayer filed an appeal challenging the order of the Controller before the Intellectual Property Appellate Board ("IPAB"). IPAB dismissed the appeal while increasing the royalty to 7%.

The approach adopted by the controller's in **Natco V. Bayer**[34] gave rise to serious concern that CCI may consider the grant of a compulsory license even in the absence of „exceptional circumstances‟. Under Competition Act, an enterprise is guilty of abusing its dominant position if it imposes unfair prices, restricts the technical or scientific development of goods or services, limits the production of goods or services, or denies market access.

The Controller in Natco pharma case granted a compulsory license, on the ground that medicine was not available to the public at a reasonably affordable price. The term „reasonably affordable price‟ was interpreted with the price of the buyer while ignoring the manufacturing cost of the company.

Refusal to license IP exclusively held by an enterprise may also be considered as a constructive refusal to supply under the provisions of the Competition Act. Such a refusal may be construed to limit the „production of goods or provision of services or market‟, or restrict the „technical or scientific development relating to goods or services to the prejudice of consumers‟, all of which amount to abusive conduct under sections 4(2) 5 of the act.

The Competition Act 2002 does not permit any unreasonable condition forming a part of protection or exploitation of intellectual property rights. According to the section 3(5) nothing in the Section 3 shall restrict the right of any person to restrain any infringement of, or to impose reasonable conditions, as may be necessary for protecting any of his rights which have been or

[34] AIR,223, 2012

may be conferred upon him by IP laws. In other words, licensing arrangements likely to affect adversely the prices, quantities, quality or varieties of goods and services will fall within the contours of competition law as long as they are not in reasonable juxtaposition with the bundle of rights that go with IPRs. Therefore the reasonability of the conditions in agreements involving IPRs has to be there to avail the exception under Section 3 (5) of Indian Competition Act or otherwise CCI may be called upon to take note of anti-competitive agreement under Section 19 of the Act and it may pass order of divesture of intellectual property or compulsory licensing under the provisions of the Act. [35]

The disagreement between the IPRs and competition law was encountered in a few cases before MRTP Commission. Section 15 of MRTP Act excluded the application of provisions of the Act to patented products similar to that of Section 3(5) of the Competition Act. In Vallal Peruman v. Godfrey Philips (India)[36] Limited the Commission observed that the provisions of the Monopolies and Restrictive Trade Practices Act would be attracted only when there is an abuse in exercise of the right protected. This principle was again reiterated in Manju Bhardwaj case [37]where the matter was related to manipulation, distortion, contrivances and embellishments etc. by way of misuse of trademarks. Thus, it can be safely deduced that even before the enactment of Competition Act 2002 the unfair trade practices emanating from misuse of IPRs were coming under the ambit of MRTP Act and similarly similar issues can be undertaken by CCI under the mandate of Competition Act 2002. In another case Mahyco-Monsanto Biotech India Limited was also indicted by MRTP Commission of unfair trade practices as it was abusing its dominant position by charging high royalty fee which made the seed exorbitantly costly to the farmers. These cases consolidate the arguments that the monopoly acquired by IPRs is prone to abuse by IPR holder and in many cases the dominant position protected by IPRs has been used to curb competition by many companies.

The Natco decision has resulted in an adverse perception of the Indian pharmaceutical industry and may adversely impact foreign investment in this sector.

[35] Naval Satarawala Chopra and Dinoo Muthappa, Competition Law International, Vol 8 No 2, August 2012.
[36] MRTP commission 1994.
[37] (1996) 20 CLA 229.

The words of Shri J. N.Rajagopala Ayyangar most aptly suits as "Patent rights were created "not in the interest of the inventor, but in the interest of the national economy", The common objective of both the law should be to promote innovation which would eventually lead to the economic development of a country however this should not be detriment to public.

For this the competition authorities need to ensure the co-existence of competition policy and IP laws since a balance between both laws would result in an economic as well as consumer welfare.

In India the concept is still not settled is still subjudise and matter is pending before the Supreme Court.

4.2 IN UK

The Fair Trading Act, 1973

This act was passed in England with a view to provide an environment for free competition. This act basically focused on the restriction of monopoly.

There is monopoly when a person or group of persons to secure the sole exercise of any known trade throughout the country. However there are certain monopolies authorized by the statute e.g. Post office with respect to carrying of letters. If there is an agreement which gives control of trade to an individual or group of individuals then it creates a monopoly calculated to enhance prices to an unreasonable extent. It is no monopoly if the control is lawfully obtained by particular persons on particular places or kinds of articles for which a substitute is available.

The competition Act of 1998 repealed the Fair Trading Act, 1973.

In UK after 2000 the competition procedure is governed by the EU competition law and any law of EU competition Commission will be governing, as UK is part of EU now and has signed the agreement in 1987 to be part of EU.

The competition law and IPR interface in Europe is regulated by European Community (EC) Competition Rules governed by EC Treaty. Articles 81 and 82 of the said rules have been the beacon of light for Section 3 and 4 of Competition Act 2002. At the heart of any application of EC competition rules to intellectual property, whether by way of Article 81 and 82 the European Commission and EC Courts have been compelled to develop a conceptual means of overcoming the national property interests protected by Article 225 of the EC treaty. This article states that the state rules governing property ownership shall remain unaffected by the provisions of this treaty.

A lot of jurisprudence has been developed in Europe over the issue by the various courts income of the landmark judgments that have laid down the foundation of law in European Union.

1) Consten and Grundig v Commission[38] In this case The ECJ drew a distinction between the existence of intellectual property rights, which could not be challenged, and their improper exercise.
2) Parke Davis v Probel & Centrafarm[39] The ECJ held that the existence of intellectual property rights did not in itself mean that a firm was dominant, although it was relevant to any assessment of dominance; the ECJ also held that a dominant firm with intellectual property rights might be guilty of abusing its dominant position, for example by charging excessive prices.
3) SCM Corp. v. Xerox Corp.[40] The court held that the conflict between the antitrust and IPR laws arises in the methods they embrace that were designed to achieve reciprocal goals.

While the antitrust laws prescribe unreasonably restraints of competition, the IPR laws reward the inventor with a temporary monopoly that insulates him from competitive exploitation of his/her protected art.

Generally, the holder of an IP right has no obligation to license their intellectual property and, in most circumstances, will not be held to violate EU competition law by unilaterally refusing to licence their IP right to competitors.

[38] [1966] CMLR 418.
[39] [1968] CMLR, 47.
[40] SCM Corp. v. Xerox Corp. , 645 F. 2d 1159.1203.

The circumstances that characterize the exercise of exclusive rights as abusive conduct were discussed by the Court of First Instance (CFI, now the General Court) in the Magill TV guide case. On appeal, the ECJ held that it is only in 'exceptional circumstances' that the exercise of an exclusive right by the holder of an IP right results in an abuse of dominance. Such exceptional circumstances were said to exist when:

• The refusal relates to a product or service indispensable to the exercise of a particular activity on a neighboring market;

• The refusal is of such a kind as to exclude any effective competition on that neighboring market; and

• The refusal prevents the appearance of a new product for which there is potential consumer demand.

Once it is established that such exceptional circumstances are present, a dominant undertaking's refusal to grant a licence may constitute an abuse of dominance, unless such refusal is objectively justified. These conditions were reiterated by the ECJ in IMS Health, where a refusal to license IP rights was held to amount to an abuse only when a competitor wished to produce new goods or provide new services on a neighboring market using such IP, for which there is potential consumer demand.

In Microsoft, where the CFI was again confronted with the issue of a compulsory licence for a protected IP right, the CFI did not require the European Commission to follow a strict application of the 'new product on a neighboring market' test. Instead, the CFI observed that if competitors were granted access to Microsoft's copyright, 'far from merely reproducing the Windows systems already on the market' competitors would offer products which 'will be distinguished from those (Microsoft) systems with respect to parameters which consumers consider important'. Thus, the CFI found that the new product test was readily satisfied, insofar as the products offered by competitors differed from those offered by Microsoft in terms of advanced performance, security and functionality. Consequently, the CFI judgment in Microsoft waters down the new-product test, as it held to be sufficient that such new products vary y from

the existing products in terms of certain capabilities. It was not necessary to show the creation of an entirely new product on a separate market.

The CFI's benign application of this 'new product' requirement in Microsoft has been criticized by academics and practitioners alike. In contrast, in Magill TV guide, there was clearly a new product, different in conception to all existing guides. In IMS Health, the ECJ found that refusal to licence intellectual property 'may be regarded as abusive only where the undertaking which requested the license does not intend to limit itself essentially to duplicating the goods or services already offered on the secondary market by the owner of the intellectual property right, but intends to produce new goods or services not offered by the owner of the right and for which there is potential consumer demand'. The new-product requirement stems from the balance that needs to be achieved between protecting IP rights and the incentives to innovate versus the 'protection of free competition'. The secondary market requirement thus serves as an additional condition when IP rights are at stake and provides an additional ground of protection to the dominant undertaking holding the IP right, in order to ensure that the compulsory licence is not merely issued to duplicate goods or services offered by the dominant undertaking. However, the CFI's lenient approach to the new product test seems to suggest a lesser degree of protection of IP rights than previously afforded in Magill TV guide and IMS Health.

4.3 IN US

Sherman Act, 1890

Sherman Act declared illegal all contracts, combinations or conspiracies in restraint of trade or commerce among the states or territories or with foreign nations. The basic requirement is that there should be an agreement or mutual commitment to engage in a common course of anticompetitive conduct.

Monopolize and Conspiracy to monopolize:

Section 229 of the Sherman Act outlawed (a) Monopolization (b) attempt to monopolize (c) conspiracies to monopolize

This section has two basic elements

1.) Possession of monopoly power in relevant market

2.) The willful acquitsion or maintenance of the power.

A person is not guilty of monopolization unless he has monopoly power i.e. power to control prices and exclude competition. Therefore offence of monopolization requires monopoly power and intention to monopolize, but there is no monopolization if the defendant's monopoly power grows as a consequence of superior product, business acumen or historical accident.

The competition act has included monopolization but it has not included conspiracy to monopolize. Sherman Act proscribes even attempt to monopolize.30 the difference between actual monopolization and attempt to monopolization is that in actual monopolization general intent to do act is required but in attempt to monopolize specific intent, which can be established by evidence of unfair tactics on part of defendant, is required. To establish conspiracy to monopolize three basic things are to be proved:[41]

(a) Proof of conspiracy

(b) Specific intent to monopolize

(c) An overt act in furtherance of conspiracy and there is no need to establish the market power.

Price Fixing

Competition Act has included the term association of price i.e. price fixing but it hasn't elaborated the vertical and the horizontal price fixing. If a manufacturer, by using his dominant position, fixes the price with retailer then it is vertical price fixing but if manufacturer fixes price with other manufacturer then it is horizontal price fixing. Vertical price fixing is also knows as price maintenance e.g. Agreement between a film distributor and exhibitor is illegal. A patentee cannot control its resale price through price maintenance agreements. Generally prices are fixed when they are agreed upon.

[41] *R Coco, [2008], 'Antitrust Liability for Refusal to License Intellectual Property, A Comparative Analysis and the International Setting', 12 Marquette Intellectual Property Law Review 1(2008) at p 6.*

Section 132 of Sherman Act also mentions that dissemination or exchange of price information does not itself establish a violation of section 1 rather price information coupled with criminal intent to fix the price violates section 1 of Sherman act. However a combination or conspiracy within section 1 is established where an agreement exists between competitors to furnish price information upon request.

In USA position on compulsory licensing is that " compulsory licensing for government cooperation are favored whereas compulsory licenses for the benefit of private competitors are not favored by the tradition of America statute law, except as sanctions for actual violation of the antitrust laws."

US Federal Trade Commission (FTC) vs. Ciba Geigy HO, Ciba Geigy Corp., Chiron Corp., Sandoz Corp. and Norvatis AG

The US FTC issued on 24 March 1997 a Decision concerning the merger between Swiss companies Ciba Geigy and Sandoz into Novartis. The combined entity will also control Chiron Corp., which is a biotechnology company in US. The FTC concluded that the merger would violate antitrust laws, because the merged companies are current competitors for several pharmaceutical, agrochemical and biotechnology products. The FTC required divestiture of several products, and ordered compulsory licenses of intellectual property rights for a number of other healthcare inventions. For example, Ciba Geigy, Sandoz and Chiron were required to license a large portfolio of patents, data and know-how relating to HSV to products, hemophilia gene rights and other products to Rhone-Poulenc Rorer. The new merged entity and Chiron were also required to grant non-exclusive licenses to any interested party of patents and other rights relating to Cytokine products. In the case of the non-exclusive Cytokine licenses (which involve gene therapy), and the Anderson gene therapy patent, the FTC specified that the royalties can be no greater than three per cent of the net sales price.

4.4 CONCLUSION

It can be safely concluded from above discussion that abuse of IPR is a very reasonable likelihood where an enterprise has its rights protected under Intellectual Property (IP) laws. The monopoly protected by IPRs is though permissible under laws but the fact remains that it is very much prone to abuse.

The enterprises are often tempted to indulge in to anti -competitive and exclusionary practices and they try to extend their monopoly into areas where they do not have rights protected by IPRs. Software giants like Microsoft, Seed companies like Macho Monsanto Biotech and drug manufacturers have their products under IPR protection and most of the times enterprises like these are sole manufacturer of their kind products. This kind of monopoly catapults these enterprises in to a position where they can dictate their terms over whole of the industry and sometimes which can be volatile of free competition rules.

Compulsory licensing can be seen as an effective remedy in such cases where the public interest is involved to a large extent and anti-competitive practices of companies have damaged the interest of consumers as well as competitors in legal sense.

Issues critical to nation like public health, public order and national security have been sufficient ground for compulsory licensing all over the globe but many countries have treated it as a remedy against anti-competitive practices.

The argument that compulsory licensing engenders competition is true to some extent especially for countries where innovation is not taking place. Such developing and under developed countries might do so to improve competition in some sectors of markets where a single player is abusing its dominant position but in long run it might hurt the incentive for innovation and thus, may prove anti-competitive.

There are reasonable apprehensions that the Foreign Direct Investment (FDI) may dry up if a country goes on to grant compulsory license as a regular measure for abuse of IPRs and anti-competitive practices. Therefore, as reiterated in this project the compulsory licensing must be resorted only in exceptional cases. European courts in this regard have developed an essential facilities doctrine which decides in which case compulsory licenses should be resorted to. In my opinion this doctrine sets balance between protection of IPRs and protection competition and it is worth emulating.

In India also Competition Act 2002 has given a wide mandate to CCI to impose penalties on enterprises violating free competition rules as provisioned by the Act. The powers of CCI in Section 27 (g) and 28 (2) are wide enough to incorporate compulsory licensing in to their ambit.

In absence of any precedent it can be conclusively said that compulsory licensing does fits in to the framework of Competition Act 2002. Keeping in mind the global trend it would not be anomalous if CCI passes an order of compulsory license to protect consumer welfare and fair competition.

5 COMPARISON BETWEEN UK, USA & INDIAN COMPULSORY LICENSING

5.1 Compulsory licensing in patent

A patent is an exclusive right granted to an inventor for his invention. In other words, a patent is an exclusive right to a product or a process to its creator that generally provides a unique way of doing something, or offers a new solution to a problem can be patented.

A product or process is capable of patent if it has come quality which is capable of industrial application or which has some unique invention helping the society.

The patent owner may give his assent to, or license to other parties to use the invention on prior mutually agreed terms. The owner may also sell his right to the invention to someone else, who will on the transfer become the new owner of the patent and once a patent expires which is after 20 years from the filing of the permission of the patent, the protection ends, and an invention enters the public domain and hence now anyone can commercially exploit the invention without infringing the right of the patent holder.

Compulsory licensing today mainly talk about allowing the use of such invention or patent without the consent of patent holder or by paying prior agreed price to him or with the judicial enforcement this can only be done if such patent is required for the public large for the protection of human race and that patent is not available to the public easily and is not economical possible

for public to purchase that in that case the govt. may grant compulsory licence to use that by any other company only after 3 years of the grant of such patent. This was the concept well settled in the TRIPS and other international IP organization which are working for the protection of the IP rights.

Since patent is regional right which mean it is granted in the country where you have applied for it does not have its global implementation it's an territorial right and hence if there is any dispute related to patenting of the work or compulsory licensing such issues should be dealt with the provision of the TRIPS agreement and can be enforced only in the court of law where such dispute arose.

In the region like Europe due to mutual cooperation of the countries of EU if a patent is patented in one country or in all the member country and hence the patent granted is an regional patent and not a territorial patent and can be enforced in any court of EU and the law of EU will be applicable.

In India the patent right is an regional right and can be enforced in India only it does not have global enforcement or enforcement in other part of country and is governed by the Indian patent act 1970.

USA Article One, section 8, clause 8 of the U.S. Constitution give the power to protect the patent in USA.

Patents in the US are governed by the Patent Act. 35. Code, which established the United States Patent and Trademark Office (the USPTO). The most common type of patent is a utility patent. Has duration of twenty years from the date of filing, but are not enforceable until the day of issuance. Design patents protect ornamental designs. Plant patents protect new varieties of asexually reproducing plants. To obtain protection under U.S. law, the applicant must submit a patent application to the patent office, where it will be examined by an examiner to determine if the invention is patentable. U.S. law grants to patentees the right to exclude others from making, using, or selling the invention.[42]

[42] http://www.bitlaw.com/patent/

5.1.1 In United Kingdome

Enforcement of patent is not any global right but it's a territorial right which belong to the country where you have patented the work, hence the compulsory licence is also an regional right given to the company who have applied for it, if an organization who has claimed for the compulsory licensing for particular invention it will not be a global licence but it will be regional licence and will be limited to the providing state only.

Where as in UK the situation is little different as UK is part of EU and any person can patent its invention in UK either at UK patent office or at EPO (European patent office).

Patent applications can be filed at the UK national patent office or at the European Patent Office. Alternatively, an international application may be filed under the Patent Cooperation Treaty (PCT) and later nationalized in the desired countries or at the EPO. However, now in Belgium, Greece, Ireland, Cyprus, France, Malta, Monaco, Italy, Latvia, the Netherlands, and Slovenia have "closed their national route" meaning that it is no longer possible to nationalize an international application and protection can be obtained via EPO.

So today an application for patent of compulsory licensing filed in UK is not a regional but it will be limited to all the countries around EU members and will be enforceable there.

The UK Patents Act 1977 provides for the grant of compulsory licenses only under patents in circumstances, where it can be established that there has been some abuse of the monopoly rights in relation to such patents. In practice though, compulsory licenses are rarely applied in the UK. This is because there are more effective provisions which control the abuse of a monopoly can be found in competition law. However, since UK is WTO member, its compulsory licensing regime should comply with the TRIPS agreement as is the legislation in most other economically significant countries that have a compulsory licensing regime.

The grant of compulsory licenses is governed by sections 46- 54 of the UK's Patents Act 1977 An applicant can apply to the Comptroller of Patents at the UK's Intellectual Property Office for (i) a compulsory or

(ii) The patent endorsed "licenses of right".

Applying for a compulsory licence in the UK

An application for the licensing can be made to the Comptroller of Patents in Uk for the grant of licence at any time after the expiration of three years from the date of grant of the patent. The applicant should establish the ground so provided below for the grant of it.later it's a discretion of the controller to grant it or not.

The applicant must establish one among the 3 relevant grounds for relief and after this only the Comptroller has a discretion whether to grant relief or not and, if a licence is to be granted then upon what terms and what those grounds are:

(a) Where the patented invention is a product, that a demand in the UK for that product is not being met on reasonable terms;

(b) That by reason of the refusal of the patent proprietor to grant a licence(s) on reasonable terms:

(i) The exploitation in the UK of any other patented invention which involves an important technical advance of Considerable economic significance in relation to the invention for which the patent concerned was granted is Prevented or hindered. Here, the Comptroller needs to be satisfied that the patent proprietor for the other invention is able and willing to grant the patent proprietor and his licensees a licence under the patent for the other invention on reasonable terms. Any such licence(s) granted cannot be assigned except to a person to whom the patent for the other invention is also assigned; or

(ii) The establishment or development of commercial or industrial activities in the UK is unfairly prejudiced..

There are two regimes for compulsory licenses under current legal system of UK: one for patentees who are "WTO proprietors" and other for non-WTO proprietors.

A WTO proprietor is a national or member of a WTO member country or has a real and effective industrial\establishment in such a country. Most patentees encountered in practice will be WTO proprietors. For WTO proprietors, such as a patentee who is a UK national (the "Patentee"), there are three grounds for relief:

- Where demand for a patented product is not being met on reasonable terms;
- Reason of the refusal of the Patentee to grant a licence or licenses on reasonable terms:
- The establishment and development of commercial or industrial activities in the UK is unfairly prejudiced;
- Where, by reasons of conditions imposed by the Patentee, unpatented activities are unfairly prejudiced.

5.1.2 In India

The history of Patent law in India starts from 1911 when the Indian Patents and Designs Act, 1911 was enacted In India, first modern law related to protection of patent was Indian Patents Act 1970 and which came into force on 1972. It made pharmaceutical product innovations, as well as those agro-chemicals, un-patentable in India. It allowed innovations patented elsewhere can now be freely copied and marketed in India. Further, this Act restricted import of finished formula, imposed high tariff rates and introduced strict price control regulation on goods. This Act was not beneficial to the big foreign multinational organizations and companies and was not in sync with the global patent system.

India being a member of WTO, it had to comply with the requirements under and the agreement of the TRIPS. As such the 1970 Act was required to be amended. The requirements were that a mailbox system is set up and Exclusive Marketing Rights (EMR) be allowed for granting of patent. Under the EMR, an international company would get exclusive rights to market a product in the field of pharmaceuticals and agricultural chemical products in the Indian market for a specified period (5 years). The mail box system is a box which received all applications for the patenting of pharmaceutical and agricultural chemical products. These provisions were included in the Patents Act through 1999, 2001 and 2002 amendments. The applications in the mail box were considered in 2005.

These amendments though far reaching still did not bring the Indian Patents Act in full conformity with the global intellectual property system. This conformity was introduced through the Patents Amendment Act 2005. The main provisions of this Amendment Act are:

1. Product Patent:

The Act extends product patent protection in all fields of technology, i.e. drugs, food and chemicals. Earlier only process patent was allowed which limited patent rights. For example, a process patent was awarded to the way a cure for, say cancer, is manufactured and not for the cure. This allowed the other manufacturers to produce the same cure by some other method and hence not violate patent rights of the original manufacturer. But now after the 2005 Amendment, patent is awarded to the way cancer cure is manufactured and to the cure as well.

2. Compulsory Licensing:

This is a TRIPS compliant provision empowering the governments to check and control the misuse of patents. Inspire of the existence of a patent, the govt. can invoke the compulsory license to make available the patented product to the people in case of national emergency for public non-commercial use. The govt. can also invoke compulsory licensing if it feels that the public requirements with regard to a patented product have not been met and the product is not available for the public at an affordable price.

The Act allows the patent holder to challenge the license so that he can block general production of his drug. Pre-grant and post-grant opposition clause has been provided. The Act also removes provisions relating to EMRs besides strengthening the provisions relating to national security to guard against patenting abroad of dual use technologies.

Patents Act 2005 provides that following items are not patentable:

A frivolous invention or one that claims anything contrary to established natural laws.

- An invention the use of which would be contrary to morality or injurious to public health.
- The mere discovery of a scientific principle or the formulation of an abstract theory.
- The mere discovery of any new property or new use of a known substance or the mere use of a known process, machine or apparatus unless such known substance results in a new product or employs at least one new reactant.

- A substance obtained by a mere admixture resulting only in the aggregate properties of the components thereof or a process for producing such substance.
- The mere arrangement or rearrangement or duplication of known devices functioning independently of one another in a known way.
- A method or process of testing applicable during the process of manufacture rendering the machine , apparatus or other equipment more efficient, or for the improvement or restoration of the existing machine, apparatus or other equipment for the improvement or control of manufacture .
- A method of agriculture or horticulture.
- Inventions relating to atomic energy.

Compulsory licensing under Patent.

One of the most important aspects of Indian Patents Act, 1970, is compulsory licensing of the patent subject to the fulfillment of certain conditions. At any time after the expiration of three years from the date of the sealing of a patent, any person interested may make an application to the Controller of Patents for grant of compulsory license of the patent, subject to the fulfillment of following conditions, i.e.

- The reasonable requirements of the public with respect to the patented invention have not been satisfied; or
- that the patented invention is not available to the public at a reasonable price; or
- That the patented invention is not worked in the territory of India.

It is further important to note that an application for compulsory licensing may be made by any person notwithstanding that he is already the holder of a license under the patent.

For the purpose of compulsory licensing, no person can be stopped from alleging that the reasonable requirements of the public with respect to the patented invention are not satisfied or that the patented invention is not available to the public at a reasonable price by reason of any admission made by him, whether in such a licence or by reason of his having accepted such a licence.

The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not available to the public at a reasonable price, may order the patentee to grant a licence upon such terms as he may deem fit. However, before the grant of a compulsory license, the Controller of Patents shall take into account following factors:

- The nature of invention;
- The time elapsed, since the sealing of the patent;
- The measures already taken by the patentee or the licensee to make full use of the invention;
- The ability of the applicant to work the invention to the public advantage;
- The capacity of the applicant to undertake the risk in providing capital and working the invention, if the application for compulsory license is granted;
- As to the fact whether the applicant has made efforts to obtain a license from the patentee on reasonable terms and conditions;
- National emergency or other circumstances of extreme urgency;
- Public noncommercial use;
- Establishment of a ground of anti-competitive practices adopted by the patentee.

The grant of compulsory license cannot be claimed as a matter of right, as the same is subject to the fulfillment of above conditions and discretion of the Controller of Patents. Further judicial recourse is available against any arbitrary or illegal order of the Controller of Patents for grant of compulsory license.

Instances of Compulsory Licensing in India thus Far

India's first and only compulsory licence till date was granted by the Patent Office on March 9, 2012, to Natco Pharma, an Indian company, for the generic production of Bayer Corporation's Nexavar, a drug used for the treatment of Liver and Kidney cancer. The three grounds mentioned under Section 84 of the Indian Patent Act were all met, i.e. Bayer's drug left the reasonable requirements of the public were unsatisfied, it was not available to the public at a reasonably affordable price, and the patented invention was not being worked in the territory of India. While

Bayer offered the drug at the cost of Rs. 2.8 lakh for a month's therapy, Natco Pharma had offered to sell the medicine at merely a fraction of that cost (Rs. 8,800). The decision of this case indicated that as opposed to maintaining an extremely strict patent protection regime, the interest of public at large would be given more importance by the government. However, the decision also invited harsh criticisms from the large group of multinational companies, who felt that the issue of compulsory licenses ought to be exercised in an even more stringent manner.

More recently, Mumbai-based BDR Pharmaceuticals has been seeking the grant of compulsory licence for the generic production of US drug maker Bristol-Myers Squibb's anticancer drug Dasatinib, sold under the brand name Sprycel. The Patent Office rejected BDR's application on the grounds that the company did not make enough efforts to obtain a voluntary licence for the drug. While this rejection was lauded by the international community and the multinational companies in particular, it seems that the issue of a compulsory licence for the drug may very well be on the cards, as citing the emergency of a public health crisis under Section 92 of the Patent Act, the Health Ministry has reportedly sought a waiver of patent rights for Dasatinib. Through a letter to the Department of Industrial Policy and Promotion (DIPP), the Health Ministry has allegedly stated that the cost of producing the drug will be met through government schemes and that around half-a-dozen schemes will be initiated to fund the cost of making the drugs available to patients for public non-commercial use.

5.1.3 In USA

Patents in the United States are governed by the Patent Act (35 U.S. Code), which established the United States Patent and Trademark Office (the USPTO). The most common type of patent is a utility patent. Utility patents have duration of twenty years from the date of filing, but are not enforceable until the day of issuance. Design patents protect ornamental designs. Plant patents protect new varieties of asexually reproducing plants.

To obtain protection under U.S. law, the applicant must submit a patent application to the USPTO, where it will be reviewed by an examiner to determine if the invention is patentable.

U.S. law grants to patentees the right to exclude others from making, using, or selling the invention.

The United States' patent system grants patents on inventions in which three classes of requirements have each been met: requirements as to the invention, requirements as to the application, and requirements as to the applicant.

1. Utility
2. Novelty and
3. non-obviousness

Who May Apply For a Patent?

According to the law, the inventor, or a person to whom the inventor has assigned or is under an obligation to assign the invention, may apply for a patent, with certain exceptions. If the inventor is deceased, the application may be made by legal representatives, that is, the administrator or executor of the estate. If the inventor is legally incapacitated, the application for patent may be made by a legal representative (e.g., guardian). If an inventor refuses to apply for a patent or cannot be found, a joint inventor may apply on behalf of the non-signing inventor.

If two or more persons make an invention jointly, they apply for a patent as joint inventors. A person who makes only a financial contribution is not a joint inventor and cannot be joined in the application as an inventor. It is possible to correct an innocent mistake in erroneously omitting an inventor or in erroneously naming a person as an inventor.

Officers and employees of the United States Patent and Trademark Office are prohibited by law from applying for a patent or acquiring, directly or indirectly, except by inheritance or bequest, any patent or any right or interest in any patent.[43]

Provisional Application for a Patent

Since June 8, 1995, the USPTO has offered inventors the option of filing a provisional application for patent, which was designed to provide a lower-cost first patent filing in the

[43] http://www.uspto.gov/

United States and to give U.S. applicants parity with foreign applicants. Claims and oath or declaration are NOT required for a provisional application. A provisional application provides the means to establish an early effective filing date in a patent application and permits the term "Patent Pending" to be applied in connection with the invention. Provisional applications may not be filed for design inventions.

The filing date of a provisional application is the date on which a written description of the invention, and drawings if necessary, are received in the USPTO. To be complete, a provisional application must also include the filing fee, and a cover sheet specifying that the application is a provisional application for patent. The applicant would then have up to 12 months to file a no provisional application for patent as described above. The claimed subject matter in the later filed no provisional application is entitled to the benefit of the filing date of the provisional application if it has support in the provisional application.

If a provisional application is not filed in English, and a no provisional application is filed claiming benefit to the provisional application, a translation of the provisional application will be required. See title 37, Code of Federal Regulations, Section 1.78(a) (5).

Provisional applications are NOT examined on their merits. A provisional application will become abandoned by the operation of law 12 months from its filing date. The 12-month pendency for a provisional application is not counted toward the 20-year term of a patent granted on a subsequently filed no provisional application that claims benefit of the filing date of the provisional application.

A surcharge is required for filing the basic filing fee or the cover sheet on a date later than the filing of the provisional application. Unlike no provisional utility applications, design, plant, and provisional applications can still be filed by mail or hand-delivery without having to pay the additional $400 non-electronic filing fee. Design and provisional applications can also be filed via EFS-Web. Plant applications, however, are not permitted to be filed via EFS-Web.

Publication of Patent Applications

Publication of patent applications is required by the American Inventors Protection Act of 1999 for most plant and utility patent applications filed on or after November 29, 2000. On filing of a

plant or utility application on or after November 29, 2000, an applicant may request that the application not be published, but only if the invention has not been and will not be the subject of an application filed in a foreign country that requires publication 18 months after filing (or earlier claimed priority date) or under the Patent Cooperation Treaty. Publication occurs after the expiration of an 18-month period following the earliest effective filing date or priority date claimed by an application. Following publication, the application for patent is no longer held in confidence by the Office and any member of the public may request access to the entire file history of the application.

As a result of publication, an applicant may assert provisional rights. These rights provide a patentee with the opportunity to obtain a reasonable royalty from a third party that infringes a published application claim provided actual notice is given to the third party by applicant, and patent issues from the application with a substantially identical claim. Thus, damages for pre-patent grant infringement by another are now available.

Compulsory licensing in patent

In the United States, the U.S. Government and its contractors can infringe patents, the only remedy available to patent holders being a lawsuit in the Court of Federal Claims. It is the policy of the U.S. Department of Defense to allow contractors to infringe patents and to defend the contractor against patent infringement claims at Government expense.

Use of this provision by agencies other than Department of Defense is rare. During the 2001 anthrax attacks through the US Postal Service, the US Government threatened to issue a compulsory license for the antibiotic drug ciprofloxacin, if the patent owner, Bayer, didn't lower the price to the government. Bayer lowered the price and the government backed down on the threat.

5.2 COPYRIGHT LAW AND COMPLSORY LICENSING

Copyright is legal and assignable rights given to a creator or author of an original work over his creation to enjoy, use, distribute with cost or without cost usually given for limited time. This is

an exclusive right give to author or creator for his literature work, musical work but also some limitations which are provided under exceptions to the copyright act of the country.

Copyright include any literary, cinematographic, dramatic, artistic, musical, sound recording, literary words also include computer programs or as called in Europe authors right.

The objective of the copyright law is to promote the progress of science and useful act and to reward the labour of author.

The author or a copyright get his right as soon the work is created an idea cannot be copyrighted. The ownership that copyright law grants has several rights that can be performed, as the owner, exclusively. Those rights are:

- The right to reproduce his work
- Prepare derivative works of the same work
- Distribute his work
- Perform his work in the manner he wants to.
- Display the work.

This is the right of an author unless he has not given it to up or sold it, it is same as the owner of car. He can sell it, lend it to someone destroy it as you are the creator of it and you have authority to whatever you want to do with it for the limited period of time.

In **India** a person can get the copyright for a work which extends throughout the life of the author and 60 years from the year in which the author dies, 60 years will be calculated from the next calendar year when the author die. Where as in **U.K. it** 70years after the death of the author. In USA has 95 years from the first publication or 120 years from the creation of the work, whichever is shorter or lifespan+ 70 years same as in UK.

The History of Copy right can be traced back in 1710 when the first time the monopoly was granted to the printers of the books. Initially it was applied only to the copying of the books and with the time it has grown to other subjects also and now has grown to pictures, movies, and audios.

Copyright are exclusive rights granted to the author or creator of an original work, including the right to copy, distribute and adapt the work. Copyright does not protect ideas, only their expression or fixation. In most jurisdictions copyright arises upon fixation and does not need to be registered. Copyright owners have the exclusive statutory right to exercise control over copying and other exploitation of the works for a specific period of time, after which the work is said to enter the public domain. Uses which are covered under limitations and exceptions to copyright, such as fair use, do not require permission from the copyright owner. All other uses require permission and copyright owners can license or permanently transfer or assign their exclusive rights to others.

Copyright is an exclusive right granted to the owner of the copyright, the person who has created it will enjoy a global right and any person who wants to use that work should take permission from the crater of that copyright owner.

The Compulsory licensing in the copyright originated from Berne Convention which was first established in 1886, and was subsequently re-negotiated in 1896 (Paris), 1908 (Berlin), 1928 (Rome), 1948 (Brussels), 1967 (Stockholm) and 1971 (Paris). This convention is relates to literary and artistic works, which includes films, and the convention requires its member states to provide protection for every production in the literary, scientific and artistic domain.

The Berne Convention has a number of core features, including the principle of national treatment, which holds that each member state to the Convention would give citizens of other member states the same rights of copyright that it gave to its own citizens (Article 3-5).[44]

Other features are as establishment of minimum standards of national copyright legislation in that each member state agrees to certain basic rules which their national laws must contain.

Member state should provide minimum 50 years of protection to the creator of the copyright of its state.

Another important minimum rule established by the Berne Convention is that copyright arises with the creation of a work and does not depend upon any formality such as a system of public

[44] MacQueen, Hector L; Charlotte Waelde and Graeme T Laurie (2007). Contemporary Intellectual Property: Law and Policy. Oxford University Press. p. 37. ISBN 978-0-19-926339-4.

registration (Article 5(2)). At the time some countries did require registration of copyright, and when Britain implemented the Berne Convention in the Copyright Act 1911 it had to abolish its system of registration at Stationers' Hall.[45]

The Berne Convention focuses on authors as the key figure in copyright law and the stated purpose of the convention is "the protection of the rights of authors in their literary and artistic works" (Article 1), rather than the protection of publishers and other actors in the process of disseminating works to the public. In the 1928 revision the concept of moral rights was introduced (Article 6bis), giving authors the right to be identified as a and to object to derogatory treatment of their works. These rights, unlike economic rights such as preventing reproduction, could not be transferred to others.

The Berne Convention also enshrined limitations and exceptions to copyright, enabling the reproduction of literary and artistic works without the copyright owner's prior permission. The detail of these exceptions was left to national copyright legislation, but the guiding principle is stated in Article 9 of the convention. The so-called three-step test holds that an exception is only permitted "in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author". Free use of copyrighted work is expressly permitted in the case of quotations from lawfully published works, illustration for teaching purposes, and news reporting (Article 10).[46]

5.2.1 IN INDIA

Compulsory license is the term generally applied to a statutorily license to do an act covered by an exclusive right, without the prior authority of the right owner. Compulsory license provisions afford the facility of using protected material in certain circumstances, as provided by statute, without seeking the prior permission of the right owner. Some of the terms (for instance those regarding rates of payment) may be fixed by the court, or a tribunal, outside the provisions of the statute. The legislator, in introducing such provisions, has often sought a means to establish a fair

[45] ibid
[46] Supra

rate for the royalties to be charged, and a system for avoiding abuse of exercise of rights in a monopoly situation.[47]

Article 9 of the Berne Paris Text provides the basis for the provisions concerning compulsory licensing. This provision provides the Convention's exclusive basis for equitable remuneration and provides for the conditions which should be met before a member country can entirely excuse a use which includes the equitable remuneration and not prejudicing the reasonable interests of the author.[48]

Section 31(1) provides for the compulsory license of the Indian work and provides the authority to the Copyright Board in this regard. The Copyright Board, a quasi-judicial body, was constituted in September 1958. Adjudication of disputes pertaining to grant of Licenses in respect of works withheld from public falls within the jurisdiction of Copyright Board. The Copyright Board was reconstituted under the Chairmanship of Dr. Raghbir Singh for a period of five years with effect from 5thApril, 2006 till the year 2011.

The section provides that after the publication of any Indian work, on satisfaction of certain conditions, the Copyright Board may direct the Registrar of Copyrights to grant a license for that particular work subject to the payment of compensation to the holder of copyrights license (which may be fixed by the Copyright Board).[49]

The conditions that need to be satisfied are:

1) The work for which the copyright is being claimed must have been published or performed in public.
2) The author must have refused to allow the publication or performance of the work in public or in case of sound recording has laid down unreasonable conditions.
3) The work is held from the public by reason of such refusal.

[47] *Karandeep Makkar* and *Daksh Mitra*, Compulsory Licensing of Copyrights: Public Interest and the Entertainment Industry, ILJ.
[48] supra
[49] supra

The objective behind the section is to provide for the mechanism to prevent the abuse of monopoly by the copyright holder and to ensure that the general public is not deprived of the copyrighted work, solely because of the unreasonable demands of the copyright holder.[50]

The Copyright Board has been conferred certain powers under this section:

I. The Copyright Board may hold an enquiry as to whether a compulsory license may be issued to the complainant to republish the work, perform the work in public or communicate the work to the public by broadcast, the Copyright Board is to direct the Registrar of Copyrights to grant such a license on its being satisfied that the grounds for such refusal are not reasonable;
II. The Copyright Board has been authorized to fix the amount of compensation to be paid to the owner of the copyright for republishing the work, or for performing the work in public or for communicating the work to the public by broadcast, and the board may determine such other terms and conditions which would be applicable for granting such license to the complainant.
III. Thus, the justification of compulsory licensing is based on drawing a mid-line on a spectrum where the market domination is one side and the incentive-less intellectual property system is on the other side.[51]

In the case, the jurisdiction of the Copyright Board under Section 31 of the Copyright Act, 1957, to direct the owner of a copyright in any Indian work or a registered copyright society to issue compulsory licenses to broadcast such works was questioned, where such work is available to the public through radio broadcast. While PPL argued that a compulsory license could issue only if the "work" had never been made available to the public earlier, the radio stations argued for an almost automatic Compulsory licence ground i.e. it was to be granted upon request and the only point for consideration was a determination of "reasonable royalty". In an elaborate judgment, Justice Sinha held in favor of the latter interpretation.

[50] supra
[51] supra

A second issue was whether such a compulsory license can be issued to more than one complainant in the light of Section 31(2)? Here again, although a literal reading of the section made clear that there could only be one such applicant, the court held that, "Sub-section (2) of Section 31 would lead to an anomalous position if it is read literally. It would defeat the purport and object of the Act. It has, therefore, to be read down. Purposive construction therefore may be resorted to." The case was referred back to the copyright board for determining "appropriate" royalties.

While the judgment faced some criticism, it came as a positive development for the FM radio industry. The decision also put the ball back in the Copyright Board's court for deciding royalties, a decision on which would alleviate the need for any future negotiations between radio stations and the record labels or collecting societies.

The dispute between the Copyright Society PPL & radio stations was decided by the Copyright Board on the 25th of August, 2010, and the board ordered all music owners in the country to compulsorily licence all of their music to the radio station/applicants at a fixed 2% royalty. This was immediately challenged in a number of petitions and appeals.

5.2.2 UNITED KINGDOM.

The concept of Copyright law was originated in the United Kingdom from common law; and It became statute with the passing of the Copyright Act 1911. The current act is the Copyright, Designs and Patents Act 1988.

The EEC harmonies the copyright laws and came up with the decision to apply common standard for the protection of copyright in 1991. A common term of copyright protection, 70 years from the death of the author was established in 1993.

On 1 June 2014 the UK government adopted three new statutory instruments, amending the Copyright act of 1988. Implementing EU Directive 2001/29, these statutory instruments updated the exceptions and limitations to the rights of performers and copyright around Research, Education, Libraries and Archives; Disability; and Public Administration.

The updated Research, Education, Libraries and Archives regulation extends the copyright exception for students and libraries from just literary and artistic works to all forms of copyright works. Fair dealing still applies. For works that need to be preserved, cultural works can be digitized by libraries, archives or museums for users to view at dedicated terminals for private study or personal research. Text and data-mining will also be permitted for non-commercial research purposes, where the researcher has the right to access the material. The existing exception for fair dealing for instruction purposes is extended to include copying of small amounts of material using modern technology, rather than just by hand.

5.2.3 UNITES STATES OF AMERICA

The terms of copyright protection totally depends upon the date of creation of that work. A work created on or after January 1, 1978, is ordinarily protected by copyright from the moment of its creation until 70 years after the author's death. Works made for hire, anonymous works and pseudonymous works the duration of copyright is 95 years from publication or 120 years from creation, whichever is shorter.[52]

[52] https://www.copyright.com

There are several different compulsory license provisions in United States copyright law, including for non-dramatic musical compositions, public broadcasting, and retransmission by cable systems, subscription digital audio transmission, and non-subscription digital audio transmission such as Internet radio. The compulsory license for non-dramatic musical compositions under Section 115 of the Copyright Act of 1976[53] allows a person to distribute a new sound recording of a musical work, if that has been previously distributed to the public, by or under the authority of the copyright owner. There is no requirement that the new recording be identical to the previous work, as the compulsory license includes the privilege of rearranging the work to conform it to the recording artist's interpretation. This does not allow the artist to change the basic melody or fundamental character of the work In order to take advantage of this compulsory license the recording artist must provide notice and pay a royalty. [54] The notice must be sent to the copyright owner, or if unable to determine the copyright owner, to the Copyright Office, within thirty days of making the recording, but before distributing physical copies. Failure to provide this notice would constitute copyright infringement. In addition to the notice to the copyright owner, the recording artist must pay a royalty to the copyright owner. This royalty is set by three copyright royalty judges. Though the compulsory license allows one to make and distribute physical copies of a song for a set royalty, the owner of the copyright in the underlying musical composition can still control public performance of the work or transmission over the radio. If the underlying musical work is well known, the work can be licensed for public performance through a performance rights organization such as ASCAP, BMI, or SESAC.

According to Register of Copyrights Marybeth Peters, use of the section 115 license prior to the 1995 enactment of the Digital Performance Right in Sound Recordings Act was extremely rare, with the U.S. Copyright Office receiving fewer than 20 notices of such licenses per year. By 2003, that number had risen to 214, which, while higher, was not considered by the Register to be significant.[55]

[53] 17 U.S.C,

[54] http://www.copyright.gov/

[55] Peters, Marybeth (2004-03-11). "Statement of Marybeth Peters The Register of Copyrights before the Subcommittee on Courts, The Internet and Intellectual Property of the House Committe [*sic*] on the Judiciary"

6 Conclusion

On the basis of above analysis it can be concluded that the compulsory licensing has become a typical feature for the modern world; it has also been adopted in the field if IPR including Copy right and Patent. Developed nations has very active in protecting the rights by relying on licenses in order to limit exclusive rights and prevent or provide remedy fir abusive practices in several areas. In both the country being it developed and developing, the compulsory licensing can be granted in various fields by the government.

The compulsory license system is not very old and has seen the recent development, as proven by recent legislative changes in developed as well as developing countries. Recent case law has also invigorated the use of compulsory licenses in several areas of intellectual property.

Though the application received for the grant of compulsory licence is very less only the United States has seen the large no. of compulsory licenses. This does not mean that the system does not influence patent owners' behavior. The vitality of the system would seem to indicate that it is a tool that may be useful in a variety of circumstances in order to mitigate the restrictive effect of exclusive rights and strike a balance between the title-holders' interests and those of the public in the diffusion of knowledge and the access to, and affordability of the outcomes of, innovation and creativity.

The TRIPS agreement talk about granting of the compulsory licensing only when certain condition are fulfilled like the inventor or creator has been duly informed about it and offer for the payment of compensation or royalty has been made as per TRIPS agreement, it does not provide any strict provision related to the implantation of compulsory licensing the trips agreement talk about the compulsory licensing should vary on the basis of case to case basis and if some medicine is lifesaving drug and not available in the developing country at an affordable price it should be allowed to grant compulsory licensing.

The Developed Country on which the compulsory licence is granted has been reviewed above, which illustrate importance of grant of compulsory for the protection of the public interests at large.

It has been the major concern for the industries and they kept raising their f voice several times for their rights. The developed countries' business community, pharmaceuticals lobbies and government against compulsory licenses as a deviation from acceptable standards for intellectual property rights, are not reflected in the policies actually applied in such countries.

Conclusions which can be drawn from the previous analysis about the compulsory licensing in the developing and developed countries are:

1. Compulsory licenses should be considered as an essential element in patent laws and other intellectual property regimes. Developing countries should disregard any attempts by developed countries to limit under bilateral or other agreements the scope of and grounds for compulsory licensing.
2. Developing Country are economically weak and cannot invest its resources on the pharmaceutical industries for the development of medicines related to any decease as it involve lots of financial capital and hence they should be allowed to license the lifesaving drugs for protecting the life of humans.
3. Thirdly, the grounds and conditions for compulsory licenses should be carefully determined by national laws. The extent to which such licenses would be available and effective depends on the provisions of national legislation and on its adequate administration by informed national authorities.
4. Fourthly, developing countries should preserve the maximum possible freedom under international rules to design their compulsory licensing systems, according to their own interests and needs, including in such areas as the protection of health and the environment, and the promotion of transfer of technology and local industrialization. Should the issue of compulsory licenses be included in the agenda of possible future negotiations in WTO, developing countries should seek to clarify the scope for the granting of such licenses in certain cases (e.g. of non-exploitation), as well as to remove some of the restrictive conditions imposed by the said TRIPs Agreement, notably under Article 31. G.

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