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Application Of Compulsory License Under Indian Patent Act-1970- Post Analysis 2005

Purvi Singh

Abstract: ***This paper tries to draw an importance of the Application of Compulsory Licenses as a tool of Patent Law, as India face mainly major problems:-***

- ✓ ***This branch of law protects some of the finer manifestations of human achievement and it also shields small and epherieral also provides justice to the public.***
- ✓ ***Looking at the Indian patent system the applicant always puts an effort to acquire voluntary License first from the patent holder but denial of such License from the patentee brings the concept of compulsory license in to picture.***
- ✓ ***The high cost involved in prosecuting or defending a case of any intellectual rights in a court of law, due to heavy court fee, lawyer's fee and incidental charges concept is introduced.***
- ✓ ***Compulsory licensing is a legally recognized means to overcome obstacles in accessing affordable medicines and subsequently increases public access to generic drugs***

Since Compulsory License has a positive contributory role in the administration of justice to the manufacturers and public at large. It supplements the efforts and work of the courts. Area of contribution chosen for the purpose specially concerns and helps the manufacturers, countries which are least developed, common man, the poor, backward and the needy-most sections of the society.

Along with it this paper also talks about the legislation pertaining to Compulsory License in India, its procedure and the concept of applied under the Patent Law and the critical study of the scope of judicial review of their decisions such as in the case of Novartis v Bayers case.

This paper basically tries to explain the concept of Compulsory License in totality by doing a critical study of the developments made in the field of Intellectual Property mechanism in the contemporary time. This paper conclusively expresses the view that Compulsory License is one of the best way to reduce the ever growing misuse of exclusive rights these days, entrusted on the potential owners of such IP rights.

I. INTRODUCTION

Intellectual property helps to devalue the grandiloquence inherent. This branch of law protects some of the finer manifestations of human achievement and it also shields small and epherieral. The main aim in shaping intellectual property policy lies in securing outcomes that are proportionate to the aim of that protection.

Number of structures utilization of protected innovation co together are a definitive controller of rivalry and licenses. Scholarly incorporates copyrights, licenses, mechanical Designs, topographical signs, trademark and so forth which are basically negative. They are the rights to stop others doing certain things rights as it were to stop privateers, forgers, imitators and even in situations where the gathering who freely made similar thoughts from misusing them without the permit of the correct proprietor. A patent is not required to be exploited by own inventions. Intellectual property is a special category of rights which protects the intellectual labor and creative labor and its outcome for a specified period of time.

The very basic important tool for the technological, economic and industrial development of the country are intellectual property rights. In modern times Patents have been recognized relevant and essential to promote inventiveness and also to ensure adequate returns on the investments made in order to remove or reduce the competition in the field. patents has also become an important source of scientific and technological information appropriate utilization of which

kindles new ideas and consequently helps in developing new inventions. As indicated by dark's law word reference patent right has been characterized as a privilege secured by a patent, typically meaning a privilege to the elite make, utilize and offer of a development or protected article.

Patent frameworks are not made in light of a legitimate concern for the creator but rather the interests of a national economy. Patent restraining infrastructures for innovations from the prior circumstances have been concerned a great deal more with empowering fabricate inside the nation than with the empowering the production of the development itself. The question of the patent concede is to empower developments as well as to see that the innovations are worked in India on a business scale. Licenses are not conceded simply to empower patentees to appreciate a restraining infrastructure for the importation of the protected article. These standards have gotten statutory acknowledgment in the scholarly administration.

A. HISTORICAL BACKGROUND OF COMPULSORY LICENCE UNDER INDIAN LAW

In order to understand a historical background of Compulsory License we need to look deeply and observe the changes brought about in these years. For appreciating the provisions of Compulsory Licensing in India a patent for invention has always been the sole creation of statutes of Indian Legislature. Thus it is essential to go back in past and know the concept and evolution of issuance of compulsory license and its use.

B. LORD MACAULAY LAW COMMISSION 1856

In 1856 the first act was passed for patent on the recommendations of the Lord Macaulay Law Commission. Such commission granted certain exclusive privileges to the creators who manufactured novel product for the period of 14 years. It was regarded as the very first patent legislation but was found defective and was required to be re-enacted with modifications under the Act of 1859. 1859 Act was enacted on the basis of British Patent act 1852. Successive amendments were made.

There are number of patent regimes In India which computes the development of Indian Patent act as follows

- ✓ The Indian Patents and Design Act 1911.
- ✓ The Tek Chand Committee Report.
- ✓ The Ayyangar Committee Report.
- ✓ The Patents Act 1970
- ✓ The Patents (Amendment) Act 1999.
- ✓ The Patents (Amendment) Act 2002.
- ✓ The Patents (Amendment) Bill 2003
- ✓ The Patents (Amendment) Ordinance 2004.
- ✓ The Patents (Amendment) Act 2005.

C. AMENDMENTS AND CHANGES INTRODUCED LEGISLATIONS ENACTED AS FOLLOWS

a. THE INDIAN DESIGNS ACT OR THE PATENT ACT 1911

The very starting Act for the incorporation of the concept Required License and for the protection of patent The Patents Act 1911 was established for the first time. It was incorporated under the management of the controller of Patents. It is also known as "The Indian Patent Designs Act 1911".

The main reason and objective for the establishment of this Act was to protect and prevent the inventions misuse and also the exclusive right of the patent holder.

The act states that on the expiration of 3 years any party who is interested in the invention can file an application with the controller of Patents to grant a License known as Compulsory License. The reasons for the applications are as follows:

- ✓ The first reason is that it lacked in the working of patent. it means that the patented invention did not work commercially in the territory of India and also it failed to work to the full satisfaction termed to be reasonable practicable.
- ✓ The second reason is that the protected development did not meet the satisfactory degree India that a demand for the patented article in India or it is gotten by importation from different nations
- ✓ If there is a refusal on the part of the patent holder on any desired reasons and when there is no provision of export to an article which India manufactures.
- ✓ The last and the most important reason was that the patent was unfairly prejudiced because of patented article or process, or either its sale of materials protected of materials for sale in case of patent.

This Act was introduced and devised on the basis of British rule before 1950 i.e. Independence. But technological advancement led the Indian government to bring about substantial restructuring in the patent regime and also to make it a line with the independent country's development. In 1947 India got independent from the British rule and later in 1948 a committee known as Tek Chand Committee was appointed by the Indian Government to specially examine the existing patent legislation with a view to enhance its efficacy.

b. PATENT AMENDMENT ACT OF 1950 / TEK CHAND COMMITTEE

The second very important legislation was introduced in 1950 adopted by the committee of Tek Chand in 1948. The legislation was brought in to analyze the disadvantage of the previous act which defended the interests of the Public in the availability of food and medicines.

The previous act was not that competent to prevent abuse of patents in the field of medicines and food therefore it gave the compulsory License provisions a due importance.

Hence the committee found that the existing provisions of the previous act 1911 was not sufficient to deal with the patent abuse in food and medicines.

The final report which was pending before the United Kingdom parliament suggested that the compulsory License should be made after 3 years by making an application to the controller of the Patents.

The grounds on which such application can be made are as follows:

- ✓ Industry such as commercial market in India was affected drastically.
- ✓ In the patented item exports of such items were absent.

The manufacturing and commercial market was adversely affected because process was made outside India and the people were willing to work the patent.

This focus on public interest was again reiterated wh en the Act was amended yet again in 1952 to include se ction 23CC that provided for the automatic endorsement of licences of right in respect of inventions pertaining to food, medicine or drug.

Therefore it led to the further amendment and bring some more scopes under the compulsory License.

c. REPORT OF AYYANGAR COMMITTEE

The Ayyangar Committee was also appointed to reform the patent legislation in balancing the national interests and interests of the patent holder. The committee extended its scope of application and brought about appreciated suggestions.

The committee observed that Indian Patents were not worked in India and 80-9- percent of its Patent were in the hands of Foreign companies. In order to bring monopolistic competition in the market foreign companies destroyed the main content of compulsory License. It resulted specially in the industries of food, chemicals, pharmaceuticals, medicines etc.

The main controversy was on medicines because the population of general Public raised but the price of the medicines increased like hell.

Later on the Committee recognized, the provisions regarding compulsory licensing were 'wholly insufficient to prevent misuse or abuse of patent rights, particularly by foreign organizations.

- ✓ "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:
- ✓ The restriction effect of 'compulsory licensing' provisions may have encouraged a large number of voluntary licenses.
- ✓ The narrow nature of the grounds upon which a com pulsory licensing application could be agitated;
- ✓ Lack of transfer of know-how from the licensor to licensee. It must be remembered that compulsory licensing provisions do not mandate a transfer know-how;
- ✓ 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",

d. THE PATENTS ACT 1970

Finally in 1970 India established its first domestic legislation completely on Patents on the recommendations and suggestions of Ayyangar Committee. The act was amended several times in order to have compliance with the TRIPS guidelines. The amendments started with Amendment Act 1999 followed by Amendment Act 2002 and finally in 2005.

In between 1999 and 2002 Amendments Act a Bill regarding compulsory License was introduced which later lapsed owing to a change in government.

The important provisions of compulsory License is contained in chapter XVI of the 1970 Act covering sections 82 to 94. Broadly speaking, the grounds on which a compulsory license can be granted under the Act, can be sub-divided into the following categories:

- ✓ Section 84 deals with Abuse of Patents.
- ✓ Section 92 deals with Public Interests.

Together with sections 84 and 92 other provisions on compulsory licensing dealt under section 92 are also mentioned under the chapter of compulsory license.

In 2005, Patent Act, 1970 underwent relevant changes and introduced Patent Amendments Act, 2005 by introducing additional grounds for compulsory Licensing in private area such as:

- ✓ Mailbox Application for Compulsory Licensing
- ✓ Section 92A deals with Compulsory licensing of pharmaceutical patents with a view to enable exports to countries which fails manufacturing competences of such products.

In order to recognize this exceptional compulsory licensing provision that finds no parallel provisions anywhere else in the world, it is important to appreciate what 'mailbox' applications are.

PURSUANT TO A TRIPS OBLIGATION, INDIA AME NDED HER PATENT REGIME IN 1999 TO INSERT S ECTION 11

A to provide that applications claiming pharmaceutical inventions would be accepted and put away in a mailbox to be examined in 2005. These applications are commonly referred to as 'mailbox applications'. The Act provides that in the case of those mailboxapplicationsthat result in the grant of a patent, an automati compulsory licence would issue to those generic companies that made a 'significant investment' and were 'producing and marketing' a drug covered by the mailbox application prior to 2005.

Such licence was given due importance by payment of a 'reasonable royalty'. In January 2006 India received 8926 mailbox applications for compulsory License in order to be examined under the 2005 Act.

Such grounds were made compulsory licensing an important License to be issued on

- ✓ Inventions that the government found so fit to endorse;
- ✓ Inventions pertaining to food and drugs.

In 2005 Act the second most important change was Applications for compulsory Licensing for exports of Pharmaceutical Products. It deals that such provision enable to export product of pharmaceutical to the countries which lacked the capacity of manufacturing such products.

Section 92A explains as under

- ✓ Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided a compulsory licence has been granted by such country.
- ✓ The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.
- ✓ The provisions of sub-sections (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under any other provisions of this Act.

Explanation to section 92A defines pharmaceutical products as to mean any patented product or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use.

By enacting section 92A in the 2005 Act India complied with the guidelines of TRIPS and also fulfilled the twin objectives of DOHA Declaration i.e. Granting Compulsory Licenses to countries which needed them to tackle their public health problems and to ensure that such Licenses are usable by themselves or can be transferred to other countries which have the technological capability to produce the needed drugs and export them to the Licensee.

Hence we conclude that Indian patent Act was amended several times and led to the inclusion of the Concept Compulsory License for food, medicines, and Pharmaceutical products, Mailbox applications for process and product patents. The 2005 Act has extended the scope of its compulsory License by protecting the manufactured product exported to the countries who lack such manufacturing capacity.

This has widened the scope of application for granting of compulsory License to the third party or the government in order to meet with the requirements of the public at large. Such changes were brought in consideration of the consumer's interest and also to prevent from the abuse of dominance of the patents by the patent holder who exploits its exclusive right entrusted by the right of patents.

II. APPLICATION OF COMPULSORY LICENSE UNDER INDIAN PATENT ACT, 1970

A. INTRODUCTION TO COMPULSORY LICENSE

India is a socialist and sovereign country and has a diversified fields of expertise. According to the constitution features three separate spheres i.e. legislature, executive and judiciary works only to protect the interests of its people. But with the rapid change in time the international commitments made by India are getting neglected. One of such international commitments is the protection of intellectual property rights in the country according to the TRIPs agreement of WTO.

Like other developing nations, India is also a signatory country to the TRIPs regime and has a mandate to incorporate some provisions in Indian Patent regime, which are too far some extent, India has successfully amended in its patent law and other Intellectual laws. The most critical and vast provision of Patent law is Compulsory License which was incorporated for the first time in Indian Patent Act,1970 after the adoption of TRIP's regime.

International business community felt that even after being a signatory to TRIPs long back and having provisions providing about compulsory license, it was not in compliance with international standards and regulations for the protection of intellectual property since only one compulsory license has been issues till now.

Recently India has a very tough situation as it has vast disparity in the economic conditions of its citizens, and that makes it hard for the government to strike a balance between ensuring strict compliance with international standards of patent protection and properly safeguarding public health. India should worry about the realistic situation of the availability of drugs which are produces as a final result after years of research which are required for the large population. Further for the development of multinational companies to set-up production units in India, necessary environment is essentially required and must be created.

If we look at the Indian patent system the applicant always puts an effort to acquire voluntary License first from the patent holder but denial of such License from the patentee brings the concept of compulsory license in to picture.

If we trace back to the past Compulsory license was introduced in the Patent Act, 1970 in the section 83-94 but the provisions were never used as such because it was termed as deterrent to the patent holder's exclusive right.

But let's not forget the main objective of the patent granted to an invention, its main purpose is to regard the invention in the public use and for the benefit of the public at large. In the mid 90's public were not given due attention by way of charging high prices for the medicines which are essentially important to cure the disease. Indian Companies as well as foreign MNC's who manufactured medicines for the treatment of cancer, Liver ailment, Tuberculosis and other severe illness gained excessive profit by charging hike in the medicines.

People who could afford bought such medicines at the market price but relatively poor consumer couldn't afford to buy such medicines and lead to its death. After the TRIPS regime India observed such great loss of its people due to non-availability and overpriced medicines and treatment available. Therefore Post TRIPS regime the concept of Compulsory License were made issued and were given great start to overcome the misuse of the invention and the patent holders exclusive right over the invention. The kick start of compulsory License in Indian patent Regime was seen only in 2012 to the Natco.

"In Natco v Bayer case the compulsory License was granted to Bayer was to hold the bonafide in the BDR case. The grant of compulsory license is not inconsistent with the

incentive provided to the patentees. The reason for it is that compulsory license can be obtained only after expiration of 3 years of grant of patent. One of the basic jurisprudence governing the subject of IPRs lies in balancing the conflicting interest of patentee's exclusive rights and benefitting public from the invention. If we conclude that Compulsory license plays a vital role where there are certain patented inventions that are important in health of public and well-being of the community."

The license is granted only when certain conditions are satisfied, which is provided under the Indian patent Act. The Act also provides about the revocation of the compulsory license when the subjected invention is not worked in a proper manner within sufficient time period. In such cases the granted compulsory license can be revoked. Compulsory licenses can be used to decrease the burden of cost of the production, and reduce the barriers to innovation, and ultimately providing greater access to these tools for public at large. Compulsory license in India is still an emerging concept and it exists in the Indian patent laws.

Compulsory licenses of patented invention grants exclusive rights to the applicant but such rights are granted only in certain situations. The concept is still growing and till now only one compulsory license is being granted by the India. With the development some changes always occurs and hence let's hope that the compulsory license always works in a positive manner in India and thereby the IP remains protected.

a. MEANING OF COMPULSORY LICENSING

Compulsory licensing are the contracts which are involuntary in nature between a keen buyer and an unwilling seller imposed or enforced by the state. Compulsory licensing are typically the rescindment of an Intellectual right an extra ordinary legal instrument used by the state. "The trade related intellectual property rights agreement describes compulsory licensing as the authorization to use or sell the invention of the patent holder to the third person by the government.

Compulsory licensing is a legally recognized means to overcome obstacles in accessing affordable medicines and subsequently increases public access to generic drugs".

"Compulsory license is an action of a government forcing an exclusive holder of a right to grant the use of that right to other upon the terms decided by the government. The government, however, pays a royalty to the patent holder in order to compensate them for the use of their patent without their consent. Compulsory license is therefore interference in the exclusive rights of the patentee of the invention. Incentive to innovate and create new works may be diminished as a result of compulsory licensing. There must be an incentive to invent because commercialization of new ideas involves money and effort".

The amount of royalties set by the state granting a compulsory license cannot Pros and Cons of Compulsory Licensing be considered as an incentive for further research; it is no way near the potential financial benefit which the patent owner would have enjoyed on an exclusive basis. Compulsory licensing is therefore opposed by many developed countries. "The countries which implement compulsory licensing provisions are criticized by the United States and the foreign multinational firms because the licensee reaps the benefits of others research without contributing their fair share to the costs incurred on research and development".

"Compulsory licensing granted by the government maintains a strong healthy competition between generic pharmaceutical industry and big pharmaceutical giants".

B. SCOPE AND OBJECT OF COMPULSORY LICENSE

a. ABUSE OF DOMINANT POSITION

The principle question of the licenses demonstration is to allow licenses to a novel innovation so as to energize developments and the imagination of the scholarly personality of a patent holder. Licenses were not simply conceded so that the patentees appreciate the imposing business model for the importation of the protected articles. Manhandle of restraining infrastructure rights conceded only takes types of taking care of the demand for the protected articles exclusively by importation from abroad and not make protected articles locally subsequently debilitating and prejudicing the foundation of new exchange or industry or the improvement of a current exchange or industry, declining to give licenses to work the patent locally, forcing prohibitive conditions on the utilization, deal or rent of the protected terminated. To expel this detestable arrangement of obligatory working of the patent just the mandatory permitting.

The primary reason for these arrangements was to keep the man handle of imposing business model allowed by the patent. By these arrangements in conjunction with the arrangements identifying with utilization of creations for the reasons for people in general patent restraining infrastructures will be made to sub serve national interests and will stop to be a disable to modern advance.

C. LEGISLATION IN INDIAN SCENARIO-- INDIAN PATENT ACT, 1970

Licenses in India are conceded to urge innovations and are to secure that it taken a shot at a business scale. The Indian patent act guarantees that the patentee ought not to have the capacity to appreciate an imposing business model for the importation of the protected article.

The patent Act gives measures by method for mandatory permitting to guarantee that the licenses don't block the insurance of general wellbeing and sustenance and the protected Rights are not manhandled by the patentee. The necessary permitting serves to strike adjust between two unique destinations remunerating patentee for its innovations and making the protected items especially pharmaceuticals items accessible to extensive populace in creating and immature nations at a less expensive and a moderate cost.

It is an intercession system that empowers the legislature to adjust the privileges of patent holder with its commitments to guarantee working of licenses, accessibility of the items at a sensible value advancement and spread of innovative development and security of general wellbeing and nourishment.

D. PROCEDURE AND WORKING OF PATENTS IN CASE OF COMPULSORY LICENSE AND ITS REVOCATION

India being the signatory member of TRIP's agreement and WTO which is the mechanism have adopted various methods in working of patents and also widened the scope of the term Compulsory License. Indian legislation on patent have proper working of such inventions and section 82 -94 contains the definition of "patented article" and "patentee" along with the working of "compulsory license" and its special provisions. Indian Patent Act 1970 have been amended in 1999 and 2002 but only in the amendment of 2005, section 92A was added in order to extent the scope of compulsory license to operate in exceptional circumstances. The following sections deals with the procedure as follows

a. SECTION 82. DEFINITION OF "PATENTED ARTICLES" AND "PATENTEE"

This section deals with the definition of—

- ✓ "Patented Article" includes any article made by a patented process; and
- ✓ "Patentee" includes an exclusive licensee.

b. SECTION 83. GENERAL PRINCIPLES APPLICABLE TO WORKING OF PATENTED INVENTIONS

"Section 83 of the Act deals with the deals principal which are general in nature applied for the working of patent failing to other provisions of the Act-

- ✓ Patents are allowed to urge developments and to secure that the innovations are worked in India on a business scale and minus all potential limitations degree that is sensibly practicable immediately;
- ✓ They are not allowed only to empower patentees to appreciate a restraining infrastructure for the importation of the protected article
- ✓ That the insurance and requirement of patent rights add to the advancement of mechanical development and to the exchange and spread of innovation, to the common favorable position of makers and clients of innovative information and in a way helpful for social and financial welfare, and to an adjust of rights and commitments;
- ✓ That the licenses conceded don't block insurance of general wellbeing and nourishment and ought to go about as instrument to advance open intrigue particularly in areas of indispensable significance for financial and innovative improvement of India;
- ✓ That the licenses allowed don't in any capacity deny Central Government in taking measures to secure general wellbeing;
- ✓ That the patent right is not manhandled by the patentee or individual determining title or enthusiasm on patent from the patentee, and the patentee or a man inferring title or enthusiasm on patent from the patentee does not depend on practices which preposterously control exchange or unfavorably influence the worldwide exchange of innovation; and
- ✓ Patents are conceded to make the advantage of the protected innovation accessible at sensibly moderate costs to general society."

c. SECTION 84. GROUNDS FOR GRANTING COMPULSORY LICENCES

A compulsory License to work a patented invention may be granted by the controller to an interested person on one of the following grounds as follows:

- ✓ 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 reasonably affordable price, or
- ✓ That the patented invention is not worked in the territory of India.

The application of compulsory license must be entertained by the controller only after the 3 years expiration from the date of grant of such patent. Failure to satisfy the reasonable requirements of the public may arise from any one of the following causes:

An application under this section may be made by any person notwithstanding that he is already the holder of a licence under the patent and no person shall be estopped 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 worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price by reason of any admission made by him, whether in such a licence or otherwise or by reason of his having accepted such a licence.

Every application under sub-section (1) shall 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.

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 worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price, may grant a licence upon such terms as he may deem fit.

Where the Controller directs the patentee to grant a licence he may, as incidental thereto, exercise the powers set out in section 88".

d. SECTION 84(6)

Manages the application documented under this area, the Controller should consider,—

- ✓ The nature of the creation, the time which has slipped by since the fixing of the patent and the measures effectively taken by the patentee or any licensee to make full utilization of the development;
- ✓ The capacity of the candidate to work the innovation to the general population advantage
- ✓ The limit of the candidate to embrace the hazard in giving capital and working the development, if the application were allowed;

- ✓ In the matter of whether the candidate has endeavored endeavors to get a permit from the patentee on sensible terms and conditions and such endeavors have not been fruitful inside a sensible period as the Controller may regard fit:

The above provision won't be pertinent if there should arise an occurrence of national crisis or different conditions of outrageous earnestness or if there should be an occurrence of open non-business utilize or on foundation of a ground of anticompetitive practices received by the patentee.

e. SECTION 85. REVOCATION OF PATENTS BY THE CONTROLLER FOR NON-WORKING

- ✓ Where, in respect of a patent, a compulsory licence has been granted, the Central Government or any person interested may, after the expiration of two years from the date of the order granting the first compulsory licence, apply to the Controller for an order revoking the patent on the ground that the patented invention has not been worked in the territory of India or that reasonable requirements of the public with respect to the patented invention has not been satisfied or that the patented invention is not available to the public at a reasonably affordable price.
- ✓ Every application under sub-section (1) shall contain such particulars as may be prescribed, the facts upon which the application is based, and, in the case of an application other than by the Central Government, shall also set out the nature of the applicant's interest.
- ✓ The Controller, if satisfied that the reasonable requirements of the public with respe ct to the patented invention have not been satisfied or that patented invention has not been worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price, may make an order revoking the patent.
- ✓ Every application under sub-section (1) shall ordinarily be decided within one year of its being presented to the Controller.

f. SECTION 86. POWER OF CONTROLLER TO ADJOURN APPLICATIONS FOR COMPULSORY LICENCES, ETC., IN CERTAIN CASES

- ✓ Where an application under zone 84 or section 85, taking all things into account, is made in light of the way that the authorized creation has not been worked in the locale of India or on the ground indicated in fragment 84(7)(d) and the Controller is fulfilled that the time which has slipped by since the fixing of the patent has for any reason been inadequate to empower the development to be taken a shot at a business scale to a satisfactory degree or to empower the innovation to be so attempted minus all potential limitations degree that is sensibly practicable, he may, by request, defer the further becoming aware of the application for such period not surpassing twelve months in the total as appears to him to be adequate for the innovation to be so worked: Provided that regardless where the patentee builds up that the motivation behind why a protected creation couldn't be acted as aforementioned before the date of the application was because of any State or Central Act or any administer or direction made thereunder or any request of the Government forced generally than by method for a condition for the working of the development in the region of India or for the transfer of the protected articles or of the articles made by the procedure or by the utilization of the protected plant, hardware, or mechanical assembly, then, the time of intermission requested under this sub-segment might be figured from the date on which the period amid which the working of the creation was forestalled by such Act, run or direction or request of Government as processed from the date of the application, lapses.
- ✓ No suspension under sub-area (1) might be requested unless the Controller is fulfilled that the patentee has brought with promptitude satisfactory or sensible strides to begin the working of the innovation in the domain of India on a business scale and to a sufficient degree.

g. SECTION 87. PROCEDURE FOR DEALING WITH APPLICATIONS UNDER SECTIONS 84 AND 85

- ✓ Where the Controller is, endless supply of an application under segment 84, Or segment 85, that an at first sight case has been made out for the making of a request, he should guide the candidate to serve duplicates of the application upon the patentee and whatever other individual showing up from the enlist to be keen on the patent in regard of which the application is made, and might distribute the application in the official diary.
- ✓ The patentee or whatever other individual craving to restrict the application may, inside such time as might be recommended or inside such further time as the Controller may on application (made either before or after the termination of the endorsed time) permit, provide for the Controller notice of resistance.
- ✓ Any such notice of resistance should contain an announcement setting out the grounds on which the application is restricted. (4) Where any such notice of resistance is properly given, the Controller might tell the candidate, and should provide for the candidate and the adversary a chance to be heard before choosing the case,

h. SECTION 88. POWERS OF CONTROLLER IN GRANTING COMPULSORY LICENSES

- ✓ Where the Controller is fulfilled on an application made under segment 84 that the produce, utilize or offer of materials not secured by the patent is biased by reason of conditions forced by the patentee upon the concede of licenses under the patent, or upon the buy, contract or utilization of the protected article or process, he may, subject to the arrangements of that segment, arrange the give of licenses under the patent to such clients of the candidate as he supposes fit and additionally to the candidate.
- ✓ Where an application under area 84 is made by a man being the holder of a permit under the patent, the

Controller may, in the event that he makes a request for the give of a permit to the candidate, arrange the current permit to be crossed out, or may, on the off chance that he supposes fit, rather than making a request for the concede of a permit to the candidate, arrange the current permit to be revised.

- ✓ Where at least two licenses are held by a similar patentee and a candidate for a necessary permit builds up that the sensible prerequisites of people in general have not been happy concerning some lone of the said licenses, then, if the Controller is fulfilled that the candidate can't proficiently or tastefully work the permit allowed to him under those licenses without encroaching alternate licenses held by the patentee and if those licenses include imperative specialized progression of impressive financial importance in connection to alternate licenses, he may, by request, coordinate the concede of a permit in regard of alternate licenses additionally to empower the licensee to work the patent or licenses as to which a permit is allowed under area 84.
- ✓ Where the terms and states of a permit have been settled by the Controller, the licensee may, whenever after he has worked the innovation on a business scale for a time of at the very least twelve months, make an application to the Controller for the update of the terms and conditions on the ground that the terms and conditions settled have ended up being more difficult than initially expected and that in result thereof the licensee can't work the creation aside from at a misfortune: Provided that no such application should be engaged a moment time.

I. SECTION 89. GENERAL PURPOSES FOR GRANTING COMPULSORY LICENCES

- ✓ Where the Controller is fulfilled on an application made under area 84 that the produce, utilize or offer of materials not ensured by the patent is preferential by reason of conditions forced by the patentee upon the allow of licenses under the patent, or upon the buy, contract or utilization of the protected article or process, he may, subject to the arrangements of that segment, arrange the concede of licenses under the patent to such clients of the candidate as he supposes fit and also to the candidate. (2) Where an application under area 84 is made by a man being the holder of a permit under the patent, the Controller may, in the event that he makes a request for the give of a permit to the candidate, arrange the current permit to be crossed out, or may, on the off chance that he supposes fit, rather than making a request for the allow of a permit to the candidate, arrange the current permit to be revised.
- ✓ Where at least two licenses are held by a similar patentee and a candidate for a necessary permit builds up that the sensible prerequisites of general society have not been happy as for some exclusive of the said licenses, then, if the Controller is fulfilled that the candidate can't productively or tastefully work the permit conceded to him under those licenses without encroaching alternate licenses held by the patentee and if those licenses include imperative specialized progression of impressive financial hugeness in connection to alternate licenses, he may, by request, coordinate the allow of a permit in regard of alternate licenses additionally to empower the licensee to work the patent or licenses as to which a permit is conceded under area 84.
- ✓ Where the terms and states of a permit have been settled by the Controller, the licensee may, whenever after he has worked the development on a business scale for a time of at the very least twelve months, make an application to the Controller for the amendment of the terms and conditions on the ground that the terms and conditions settled have turned out to be more grave than initially expected and that in outcome thereof the licensee can't work the innovation aside from at a misfortune: Provided that no such application might be engaged a moment time.

I. SECTION 90. TERMS AND CONDITIONS OF COMPULSORY LICENCES

- ✓ In settling the terms and states of a permit under area 84, the Controller s lobby endeavor to secure—
  - that the eminence and other compensation, assuming any, saved to the patentee or other individual helpfully qualified for the patent, is sensible, having respect to the way of the innovation, the consumption acquired by the patentee in making the creation or in creating it and getting a patent and keeping it in compel and other important components;
  - That the protected development is attempted without limitations degree by the individual to whom the permit is conceded and with sensible benefit to him;
  - That the licensed articles are made accessible to the general population at sensibly reasonable costs;
  - That the permit allowed is a non-selective permit;
  - That the privilege of the licensee is non-assignable;
  - That the permit is for the adjust term of the patent unless a shorter term is reliable with open intrigue;
  - That the permit is allowed with a dominating reason for supply in the Indian market and that the licensee may likewise send out the protected item if need be as per the arrangements of sub-statement (iii) of provision (an) of sub-segment (7) of segment 84;
  - That on account of semi-conductor innovation, the permit allowed is to work the development for open non-business utilize;
  - that on the off chance that the permit is conceded to cure a practice decided after legal or managerial procedure to be hostile to focused, the licensee should be allowed to send out the protected item, if need be.
- ✓ No permit conceded by the Controller might approve the licensee to import the protected article or an article or substance made by a protected procedure from abroad where such importation would, however for such approval, constitute an encroachment of the privileges of the patentee.
- ✓ Notwithstanding anything contained in sub-area (2), the Central Government may, if as its would like to think it is fundamental so to do, in the general population intrigue, guide the Controller whenever to approve any licensee in

regard of a patent to import the protected article or an article or substance made by a licensed procedure from abroad (subject to such conditions as it considers important to force relating among different matters to the eminence and other compensation, assuming any, payable to the patentee, the quantum of import, the deal cost of the foreign made article and the time of importation), and immediately the Controller should offer impact to the headings.

VI. ANALYSIS OF COMPULSORY LICENSE POST AMENDMENT 2005

A. INSERTION OF SECTION 92 AND 92A

a. SECTION 92. SPECIAL PROVISION FOR COMPULSORY LICENCES ON NOTIFICATIONS BY CENTRAL GOVERNMENT

The central government may by notification in the official gazette declare a compulsory license to be granted to the government in case of national emergency, extreme urgency and public noncommercial use.

Such circumstances are of special character and shall be followed in case of the patented invention where the government fits to grant such compulsory license as described under:

The License can be granted by the controller if any person interested at any time filed an application for such grant on such terms and conditions.

The terms and conditions when satisfied by the controller under section 92(1) it should be secured to the articles manufactured in order to provide such invention at the lowest prices in connection with the exclusive right of the patent holder.

Section 92(2) deals with the provisions of sections 83, 87, 88, 89 and 90 shall apply in relation to the grant of licenses under this section as they apply in relation to the grant of licenses under section 84.

It has been stipulated in section 92(3) that where the controller is satisfied on consideration of the application that it is necessary in.

- ✓ a circumstance of national emergency; or
- ✓ a circumstance of extreme urgency; or
- ✓ a case of public non-commercial use,

which may arise or is required, as the case may be, including public health crises, relating to Acquired Immune Deficiency Syndrome, Human Immune Deficiency Virus, tuberculosis, malaria or other epidemics, he shall not apply any procedure specified in section 87 in relation to that application for grant of licenses under this section 93(3). Provided that the Controller shall, as soon as may be practicable, inform the patentee of the patent relating to the application for such non-application of section 87.

b. SECTION 92A. COMPULSORY LICENCE FOR EXPORT OF PATENTED PHARMACEUTICAL PRODUCTS IN CERTAIN EXCEPTIONAL CIRCUMSTANCES

According to section 92A, is a special section which provides that compulsory License should be granted for the pharmaceutical products manufacturing and exporting to the country who lacks or has no manufacturing capacity in the fields of medicine to address the public health problems.

Therefore the compulsory license have been granted by the country or by notification allowed the importation of the medicines from India.

According to section 92A(2) If an application under section 92A(1) is received in the prescribed manner the controller shall grant a compulsory License solely for the manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be prescribed and published by the controller .

According to section 92A(3) the provisions of sub-sections (1) and (2) shall be without bias to the extent to which pharmaceutical products produced under a compulsory license can be exported under any other provision of this Act.

For the purposes of this section 92A 'pharmaceutical products' means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use.

B. ANALYSIS OF COMPULSORY LICENSING POST AMENDMENT ACT 2005 AND INCORPORATION OF TRIPS GUIDELINES

Section 92A has been inserted with the view to widen the scope of compulsory License in patent after the inclusion of Trips agreement. Amendment act of 2005 lead to the inclusion of compulsory license for the export of patented Pharmaceutical products in certain exceptional cases. The provisions were added based solely on the Declaration issued consequent on the Ministerial Conference held in Doha which is under the control of TRIPS in the year 2002.it was observed that India took a leading part in the conference and for the issuance of the declaration.

Such Declaration held that the WTO (World Trade Organization) members which acts as a mechanism regulatory of TRIPS had the right to protect public health and in particular to promote access to medicines for countries. This lead the countries government to arrive at an appropriate decision in case when there is public health crisis or national emergency or extreme urgency in the matters of public health. Subsequent to the Doha declaration following major relaxations have been made.

It was held on 27th June 2002 that the Least Developed Countries do not have to provide patent protection for pharmaceutical products till 1st January 2016. But the meeting held on 3rd August 2003 agreed by the WTO members that the poor countries can import cheaper generic drugs made under compulsory licensing, if they are unable to manufacture the such medicines. TRIPS agreement to which India is a member

explained that in Article 31 relaxation for manufacture of goods required under Compulsory Licensing was available only if the production was within the country. But such relaxation was not useful to for countries who do not have facilities, such as infrastructure and capability to manufacture the drugs within their country.

Now due to technological advancement and innovation it would be possible for such least developed countries to import such drugs from third world Countries Like India which manufactures such drugs under Compulsory Licensing and if Circumstances warrants also export such drugs to the desired poor countries.

C. SECTION 93 ORDER FOR PERMIT TO WORK AS A DEED BETWEEN GATHERINGS CONCERNED

The order grant under the Compulsory license shall be deemed to be a grant if granted as provided under any contract executed by the patentee and other necessary parties to follows the terms and conditions settled by the controller.

D. SECTION 94 TERMINATION OF MANDATORY PERMIT

The patentee or any other interested party who derives the title or interests in the patent, and whose compulsory license granted under section 84 can be terminated by the controller as and when required to the situations which arises to the grant thereof no longer exist and such circumstances are not likely to occur.

Termination acts as an objection for the compulsory licensee on whom such grant is specified.

According to section 94(2) and while reading the application, the interests of the person on whom compulsory license has been granted earlier shall not unlikely to be discriminated.

According to section 94(1) compulsory license application can be terminated in the form and manner as prescribed such as in form 21 along with the fees of rs. 1500 in case the patentee is an individual and Rs. 6000/- if the patentee is a legal entity. The copy of evidence and application shall be served on the holder of the compulsory License and also intimate the controller of the date of service to be effected.

The compulsory License holder may file an objection along with evidence if any occurs within the span of 1 month from the date of receipt of the application and evidence by him to the controller and shall serve a copy to the applicant. As specified under rule 102(3) an extension of 3 months can be availed by the opponents under special circumstances at the discretionary power of the controller. Hence required by the opponents to file the evidence within the time period as specified to avail the benefit of its interests. On the requisition of the controller or in the case of special appeal no evidence should be filed by any of the party to the controller.

As specified under rule 102(7) the controller may serve the copy of termination to both the parties if the controller terminates the compulsory license.

95-98. [Omitted by the Patents (Amendment) Act, 2002]

E. REASONS AND CONDITIONS TO BE SATISFIED TO CHALLENGE SECTION 92 A

The primary reason of such arrangement can be summoned or tested when the nation did not have the inadequacy to fabricate such pharmaceutical item and furthermore has no assembling limit can apply for the obligatory permit and offer of the pharmaceutical item in the nation.

As indicated by this arrangement the gathering looking for mandatory License under area 92A needs to make the application independently giving all the proof in support thereof. As it were the minor truth that the gathering has as of now secured an obligatory License under segment 84 of the Act won't suffice. Such a License has likewise to apply independently under segment 92A with all the proof for getting the obligatory License to send out the pertinent pharmaceuticals items under the area 92A.

On receipt of an application looking for authorization for the consent to send out the pharmaceutical items to the nation concerned, the controller, if fulfilled, will concede the permit according to the terms and conditions he considers proper. Such terms and conditions have additionally to be distributed.

The clarification given to the significance of the expression "Pharmaceutical items" in area 2(1) (ta) implies any new element including at least one innovative stride.

F. IMPACT OF COMPULSORY LICENSE IN TODAY'S WORLD

These are the impacts majorly areas which will be affected by compulsory licensing in the coming future:

a. INNOVATION

The emerging situations of issue of compulsory Licensing in the world would decline the innovative instances because it will destroy the pharmaceutical industries of the developing countries and also least developed countries. It will force it to go into the research and make it dependent on the generic medicines which are easily available at a minimal cost if we compare it to the research and development price.

The major problem will be that the developed country will never introduce its molecule patent in the developing country as well as in least developed country because there will be a risk of losing the patents essentials and they will fail to cope up with the cost of research from the market.

b. COMPETITION AND COST

Issuance of compulsory License in the country where manufacturing of generic medicines lacks will lead to the competition between the generic companies whose role is to capture the high market value. The competition between them will lead to compete among themselves to make more and more generic medicines.

Such impact will automatically cut the prices of such highly priced medicines along with the assurance of easy access for every patient who could not afford such high priced medicines. It will also force the innovators to produce such

patent molecule at a standard price in order to compete with the prices of the medicines in the market.

c. PATIENTS

The Compulsory Licensing for grant of generic medicines are very important and are helpful for the poor patients and financially challenged. These people are mainly from the developing countries as well as least Developed Countries. They cannot have sufficient access to the medicines and utilization of the technology, innovation at the desired low price for gaining god health.

Giant and successful Pharmaceutical companies are extending hands to the needy of the developing countries and the least developed countries by providing the benefit of accessing medicines and also running such programs like free access to medicine in order to protect to protect the dignity and the Patent so granted.

At the end, I conclude that the systematic impact has gained profit and acceptance. It can be evaluated at the global level also. Still there is a requirement for a methodical assessment of wellbeing understandings settlements and traditions to protect the overall health governance of the people worldwide. Therefore the countries who lacked such manufacturing and importation facility should been keen to allow such importation and bring about changes to prevent it from any further disaster.

b. INTERNATIONAL APPROACH OF COMPULSORY LICENSE

A. PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY 1883

The Paris convention is the first legal instrument for the protection of Industrial property such as Patent, Trade mark- etc. It is also known as The Paris Convention adopted in 1883 .This convention has undergone many a times under amendments but lastly the amendment took place in Stockholm in 1967.Many changes were brought regarding the patent in the amendments. The concept of compulsory License was also dealt under the convention during its reign.

The Paris Convention of 1883 envisioned provisions for each contracting State to take legislative measures for granting compulsory licenses. According to Article 5A (2) of the Paris Convention it states that Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory license to prevent the abuses that might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work. Or insufficient working.

All the special provisions for compulsory Licenses in article 5 A were only applicable for non-working or insufficient working and not to the Licenses which the national law is free to provide for. Such other types of compulsory Licenses may be granted to prevent abuses other than non-working or insufficient working. Example excessive prices or unreasonable terms for contractual licenses or other restrictive measures which hamper industrial development. It may be granted by considerations of public interests, in cases where there is no abuse by the patent owner of his rights.

Under Paris convention there are also cases where a compulsory License is provided for to protect the public interest in unhampered technological progress. This is the case of the compulsory License In favor of the so called dependent patents, if a patented invention cannot be worked without using an earlier patent for invention granted to another person then the owner of the dependent patent may have the right to request a compulsory License to enable the use of that invention.

If the owner of the dependent patent for invention obtains the compulsory License he may in turn be obliged to grant a license to the owner of the earlier patent for invention.

Paris Convention, 1883 was amended in 1979. The Convention provided for the granting of compulsory licenses by the member countries at least in cases of the non-working of a granted patent in a country or union. The national laws are not prevented by the Paris convention to provide for such compulsory Licenses, and they are not subject to the restrictions provided in Article 5A.

Thus, the concept of compulsory licensing also existed in the pre-WTO era. The main drawback of the Paris Convention was the absence of universally applicable legal provisions. Each country followed its own domestic legislation on intellectual property. There was widespread infringement of intellectual property rights. It caused considerable economic losses to the developed world. After this process of negotiation of Uruguay Round of GATT started which finally led to TRIP's agreement.

B. COMPULSORY LICENSE IN TRADE RELATED ASPECTS OF THE INTELLECTUAL PROPERTY RIGHTS(TRIPS)

As we all have well knowledge on the working of Patents and also its abuse by the exclusive right holder witnessed from past. In order to remove such dominant abuse of such patent and to enhance the inventions use in the public concept of compulsory License have been made more stringent than the past provisions through TRIPS.

TRIPS agreement deals with the mechanism of compulsory License in order to overcome patent protection and enables the other companies to produce a patented product without the voluntary permission of the patent holder. It acts as an exception to the monopoly created by patent and acts as a legal counterweight to combat the adverse effects of patents.

TRIPS guidelines authorizes the State to make use of Compulsory License according to its own discretion. Thus, the State can rightfully resort to the use of Compulsory License in order to meet health requirements of the country's population. The compulsory license allowed the generic company to manufacture and sell the drug at a part of the cost of the patented version. The move has been praised by access to medicines praised within India and internationally.

This change makes it obvious that Compulsory License can thus ensure greater access to medicines by introducing an alternative supplier in the market thereby giving the public a choice other than drugs of the patentee and also increasing the quantity of the same drug to meet the treatment demands.

The main objective of introducing Compulsory License was to make the patented drugs more affordable for the general public. It is a step forward in the right direction towards utilization of TRIPS flexibilities to address public health needs. The advent of TRIPS and India's agreement to TRIPS During the 1980's made the developed countries pursued to establish a new global trading system with the intention to maximize the profits for their multinational companies (MNCs) and thus, insisted on the inclusion of Intellectual Property Rights under the ambit of international trade rules during the Multilateral Trade Negotiations, known as the Uruguay Round, which got underway in 1986.

India was an original signatory to WTO which came into being on 1 January 1995. Under the terms of the WTO-mandated TRIPS Agreement, India was obliged to make patent protection for the first time available for process as well as products for inventions in all fields of technology. Earlier, India provided patent protection only for process patent but later on included product patent. Protection for product patents was excluded for pharmaceuticals under the then Act.

Thus, India included pharmaceuticals and agro chemicals patent protection. Further, like other legislation the minimum term of patent protection required under TRIPS is twenty years, thus significantly extending the term of protection of seven years.

Before TRIPS inclusion India had provided process patents only to medicines and lacked in the other field of science and development. According to the TRIPS it has given flexibility to the developing countries that they are not mandatorily required to follow patent standards of the developed countries.

In pursuance every member country in order to protect its patent by application of compulsory License should have its own domestic legislation then and if failed to have cannot ask for the protection in such other countries.

Article 2(1) of the TRIPS Agreement states that provisions of the Paris Convention shall be complied with by member states, thereby ensuring that the Paris Convention articles are read as part and parcel of TRIPS Agreement.

Article 8 of TRIPS states that the countries may adopt measures to protect public interests in sector of vital importance to their socio economic and technological development.

If we start with the first Article of TRIPS which deals with compulsory License is Article 27 (1) which states that patents will be available to the inventions whether product or processes in every filed of technology.it does not define the term but only provides flexibilities to use this term.

Under Article 27(2) of TRIPS, it excludes the inventions which are not patentable in order to protect public order, morality and also public health. TRIPS additionally makes a harmony between here and now lifesaving drugs and long haul protest of giving eminences to the pharmaceutical organization for the advancement of meds. TRIPS additionally forces confinements on the rights presented on the patent holder incorporating into obligatory License.

Article 31 of TRIPS deals with the term compulsory licensing in patents and stats that "other use without authorization of the right holder ". It means that authorization to use such patented invention by the third party or the government when the patent holder fails to provide with the actual purpose of the invention and when the third party fails to obtain such license voluntarily.

It also explains that the above provision cannot be availed in three situations

- ✓ National emergency
- ✓ Extreme Urgency
- ✓ Public noncommercial use.

TRIPS fails to define the term Compulsory License but in Article 31 it refers the term Compulsory License. It states that article 31 do not put any restriction on the grounds of the application for compulsory Licensing.

The most important clause for compulsory License is Article 31 clause (f) which states that "such use shall be authorized mostly for the supply of the domestic market of the member authorizing such use". This provision can only be used by the countries whose manufacturing capacity is much better and equipped than the other. It puts the limitation on the countries whose manufacturing capacity is not good as others.

Such provision limits the patent holders right by providing most important part to the countries whose manufacturing capacity is not good and limits the exclusive character to export medicines to countries with public health needs thus it bars the nation from deriving its benefits except when anti-competitive practices.

As most countries needing to make use of the patent exceptions in TRIPS failed to satisfy the needs of the countries that the exceptions were designed to benefit. There is no language in TRIPS agreement which deals with the national legislation decide the degree of flexibility in the conditions of compulsory Licensing.

TRIPS also failed to give the definition of "Non-Commercial use", "National Emergency", "Extreme Urgency" adequate remuneration etc. It also lacks in providing clear guidance on how the nations implement these provisions.

But TRIPS provides the idea to provide remuneration to the patent holder according to their economic value of the authorization but the term economic value and how it has been calculated is been defined by the TRIPS.TRIPs only explains the compulsory Licensing but does not provide at what level compulsory Licensing can be authorized to the third person or government. According to Bryan Mercuria four main areas which are not satisfactorily resolved are:

- ✓ The scope of disease and products covered under the exception
- ✓ Countries that would be eligible to use the system
- ✓ Ensuring adequate remuneration
- ✓ Safeguarding the system against diversion of drugs into the markets

Therefore now developing countries must themselves take the initiative to protect their interests. TRIPS provided favorable environment and made the scope of the patent holder restrictive and increased the scope of the public health by issuing compulsory Licenses. It also helped the member countries to incorporate domestic legislation for smooth functioning of compulsory Licensing and also working of administrative procedures to avoid Red Tapism.

TRIPS main purpose was to provide and promote cheap and widely generic medicines to cure the lifetime illness.

Compulsory Licensing was the only way through which such objective was acquired. It tremendously and effectively widened the scope of public health and also curtailed the economic interests of the patent holder. The fact of TRIPS was used to benefit the people's health and it was demonstrated in many south Asian countries Like India etc.

Unlike the TRIPS guidelines if used properly and focused on its functioning then the world and the developing countries can work towards the protecting the interests of the public with the compliance of TRIPS regime. After 1995, the developing countries were given grace period of 10 years to regulate the functioning of its domestic legislation in order to meet the requirements of the technological advancement and innovation. India is and was one of the developing countries whose legislation although present was not effective in granting patent and also for issuing compulsory License.

C. DOHA DECLARATION

At the 4th Inter Ministerial Conference held in Doha in 2001, para 6 of the Doha Declaration reiterated the fundamental tenet that public issues in member countries will supersede private interests reflected through exclusivity granted by the patent system. It endorsed the rights of the members to interpret and implement through appropriate measures and protection of public health and promotion of access to medicines subject to respective Articles 2 and 3 referring to the most favored nation treatment to nationals and non-nationals. The rights of members were also extended to determine the grounds for compulsory License define national emergencies and implement exhaustion rights.

In pursuance to Doha Declaration the patents amendment Act 2005 has inserted a new provision on Compulsory Licensing for manufacture and export of patented Pharmaceutical products into any country that does not have sufficient manufacturing capability. It helped in the addition of section 92 A to the Patent Act.

This declaration sought to issue compulsory License to the developing nations. It lays down the general principles and empowers with certain rights. Para 6 of the declaration explains that the nations insufficient or lacks manufacturing capacities in the pharmaceutical sector could face problems in making efficient use of compulsory Licensing under the TRIPS regime.

In 2003 the World trade organization announced the decision to implement para 6 of the declaration allowing a waiver of Article 31 (f)'s domestic market restriction on compliance with certain conditions. It allowed member country to issue compulsory License to produce generic medicines for export to least developed nations and other nations which establish that they have insufficient or no manufacturing capacities in the pharmaceutical sector.

Even after incorporation of Doha Declaration and the desired provision, scope of compulsory license suffered from many short comes it also prevented from the effective use of this law for access of the drugs.

It has also been noticed that many developing countries do not want to avail the benefits of compulsory license due to political reason, and some other reasons as well.

Based on the DOHA Declaration the following major relaxations have been accepted:

- ✓ It has been agreed that least developed countries (LDC) do not have to provide patent protection for pharmaceutical products. This decision was arrived at the meeting held on 22/06/2002.
- ✓ It has been agreed that poor countries can import cheaper generic drugs under compulsory Licensing they are unable to manufacture the medicines themselves. As per the earlier provisions of TRIPS Article 31, relaxation for the manufacture of goods under compulsory Licensing was available only if the production was within the country.

This provision is not considered useful for poor countries who do not have facilities to manufacture the drugs within their country. This decision was made at the meeting held on 30/08/2003.

According to the Doha Declaration such countries can import such drugs from third countries such as India which has not only the capability and infrastructure to manufacture such medicines under the compulsory Licensing but also providing them at a reasonable price. At the time limit for the completely satisfying the provisions of TRIPS was fast approaching the government introduced a bill for the comprehensive amendment of the Patents Act 1970 in the parliament on the 22nd December 2003.

The bill contained decision of section 5 resulting in the grant of patents for new products in the fields of chemicals pharmaceuticals agricultural chemicals and food. It also contained some provisions which deal with fine tuning of the existing provisions. Further the provisions based on the DOHA declaration relating to public health were also incorporated.

The occurrence of compulsory licensing experienced different view from different part of globe. Mainly developing countries are giving importance to the compulsory licensing because of inaccessibility and unaffordability of the medicines and they are continuously granting the more and more compulsory licenses. The use of generic medicines by the developing nations are increasing day by day.

On the other hand developed countries like US, Europe are opposing the compulsory licensing and are putting pressure on developing countries not to issue compulsory license as it would decline the innovation. Different instances of compulsory licenses took place all around the globe within past 12 years after Doha declaration.

By enacting section 92 A India has fulfilled the twin objectives of Doha Declaration i.e. Granting compulsory License to countries which need them to tackle their public health problems and to ensure that such Licenses are usable by themselves or can be transferred to the other countries which have the technological capability to produce the needed drugs and export them to the Licensee.

Till now India had issued hardly number of compulsory Licenses. Recently in 2012, China also had opened the way for generic drugs in the country by making an amendment to its Intellectual property laws in order to allow the government to issue compulsory licenses for local generics makers to produce drugs which are still under patent period. But there

has been no real case of compulsory licensing of patent molecule till date from china.

After the 2005 Act India has issued 5 compulsory License till date. But in the coming years developing nations have to undergo more changes and bring in connection with the developed countries. Therefore more and more due importance should be given to the issuing of compulsory licensing and also to the countries who lack the manufacturing capacity of medicines.

Natco v Bayer is the first case on issuance of Compulsory Licenses. India in 2012 issued its first Compulsory License to the company in order to work in connection with public health and promote technological advancement and innovation. Due importance to public health and non-availability of medicines or lifesaving drugs are given in India

VII. COMPARISON OF COMPULSORY LICENCE WITH OTHER DEVELOPED COUNTRIES GLOBAL PERSPECTIVE

A. COMPULSORY LICENSING IN U.S PATENT SYSTEM

Article 1 section 8(8) of the US constitution gave the power to congress to promote the progress of science and useful arts by giving limited time to the authors and granting exclusive right to the respective discoveries and findings in the US patent system. As proved the grant of patent to an invention entitles the patent holder to enjoy benefits and exclude others for exploiting such invention. The main rationales for the patent system are to promote the development and misuse of inventions, and to encourage inventors to disclose their inventions to the public.

US being the developed country was entrusted with the complete legislation for the protection of patents and hence did not give much attention to the granting of License as Compulsory licensing to the third person on the grounds that it would destroy and harm the main purpose of patent system by reducing inventor' incentive to develop new technologies and encouraging inventors to keep inventions secret.

The possibility of a compulsory license would reduce the value of the patent; therefore, inventors would be less likely to invest money to develop a new invention because the return on investment would be smaller.

Inventors would be more likely to keep the invention secret, if feasible, rather than patent it, to avoid the possibility of a license being granted. These two results would defeat the main purposes of the patent system to promote innovation and to encourage disclosure of inventions. These arguments, however, overestimate the effects of a compulsory licensing system and would only occur in a system that grants licenses very liberally.

Scherer et al. conducted another survey in 1958 of twenty-two large U.S. corporations to determine the importance to the companies of patent protection. Regarding patent licensing, there was a general willingness to license patents, with reluctance to license patents covering the companies' principal products.

When questioned as to their response to a general compulsory licensing provision, over half of the companies said it would have no effect, while about a third said that they would decrease their research activity. Thus, it seems that a reasonable compulsory licensing provision would not have much negative impact on the goals of the patent system.

After 1999 US observed the progress of Compulsory License in India because India gained a momentum after the TRIPS inclusion and started recognizing the importance of compulsory license in the field of medicines, pharmaceutical exports etc. US rarely used the term compulsory License as it lacked the separate legislation. Although U.S patent system was effective did not provide for compulsory License, but it was allowed under special legislation and under Anti- trust law.

U.S patent system is the richest in granting compulsory licenses in the case of anti-competitive practices and for the reason of governmental use. National security was also the reason for the grant of compulsory license. Patent holder of such invention were given reasonable royalty on the doctrine of willing buyer, willing seller formulation. There were cases where patent holder were not given royalty and made royalty free. The most significant character of U.S patent system is that it made patentee to declare the results of its research readily available to the other industry members and also to transfer the knowledge of it.

U.S also started granting compulsory licensing for medicine after India gave importance to the pharmaceutical industry because it was called hypocritical due to the common lack of providing affordable pharmaceuticals. The prices of medicines were so high that it led to the monopolistic competition with India and suffered a tremendous loss lead to the grant of compulsory License.

Canada allows for CLs under the Food and Drugs Act which points to the World Trade Organization guidelines. Prior to the repeal of its compulsory licensing act, Canada also had specific provisions relating to medicines, and was actually the first country to authorize the compulsory licensing of an AIDS drug for Rwanda for export.

The effectiveness of compulsory licensing in certain circumstances suggests the need for a legislative provision for compulsory licensing in the United States. This provision would allow for compulsory licensing in the case of non-use of the patent and where one patent obstructed a later one. The proposed legislation of compulsory License lead to permission of applications for compulsory licenses in two cases:

- ✓ where the invention was not being used or was not available in the United States,
- ✓ When the use of the applicants' patented invention was being blocked by a previous invention.

The above reasons lead the patentee loose the exclusive right and the public gained profit. Where the invention is not being used, the patentee gains a reasonable royalty and the public gains access to the invention. In the case of blocking patents, compulsory licensing would resolve bargaining deadlocks with either the threat or the implementation of a compulsory license forcing the original patentee to come to terms with the improver. This would help to avoid occasions where the development of important technology was delayed due to bargaining breakdown. In each case, the provision

would be used rarely enough that it should not significantly impact the incentive of parties to develop new technology. Thus, compulsory licensing would be a beneficial addition to the U.S. patent system. Recently US has entered in the domain of protecting the generic medicines after India started doing so.

B. COMPULSORY LICENSES IN FRANCE

As discussed above grant of Patent in case of medicines and other situations the main objective of such invention is to promote such innovation and safeguard the interests of the public at large. Grant of Compulsory License related to medicines has been provided in other countries such as France, Australia etc.

Same way France also sanctions compulsory Licenses when the medicines are not available to public, or available to public but in insufficient quantity or quality or at abnormally high prices. Therefore in French law compulsory license can be given on order to promote public health and ensure the availability of medicines at affordable prices. This however encourages the country to invest more and produce more for the betterment of the country.

C. COMPULSORY LICENSES IN ISRAEL

In Israel, a compulsory license can be granted, if it is necessary to assure the public of a reasonable quantity of a product capable of being used as a medicament, to manufacture a medicament or a patented process for manufacturing a medicament.

D. COMPULSORY LICENSE IN EUROPE

a. INTRODUCTION

European patent system is a model on which Indian Patent system was drafted. Unlike other countries European countries also uses Compulsory License as a countermeasure against the certain potential abuses of the patent system.

Though, most of the European countries have analogous provisions in their patent law, the regulations are by no means uniform across the region. Entire Indian Patent system has based formulated on the basis of UK patent system because the working of patents in UK was somehow matching to the conditions in India. Although not all the regions of UK follows compulsory License but the impact of such provision is so vast and proved important that the other developing countries or developed countries also wants to adopt such provisions in order to have effective and efficient working of patented inventions in lieu of the public benefit.

b. COUNTRIES UNDER WHICH COMPULSORY LICENSE WORKS?

Countries such as Austria, Spain, Netherlands, Italy and many more have the provisions of granting compulsory License. Where such provisions exist, the grounds on which a licence will be granted and the nature of, and conditions attached to, a granted licence tend to be broadly similar. In countries like Belgium, Portugal compulsory License can be granted also after the expiry of three years of grant or after the four years from the filing an application of patent.

Even in the Swiss law if the patented invention did not make an interesting change which is not sufficient to satisfy the Swiss domestic market then in that case the interested party i.e. third party may request to cancel the patent after a period of two years from the date of grant of the first License. In Netherlands and United Kingdom compulsory Licenses can be applied after the three years of the grant of the patent. Germany also give compulsory License at any time after the grant of a patent application.

The procedure of grant of compulsory License is almost same and can be applied for such Licensing only when the invention failed to provide the main objective for which it was granted.

c. APPLICATION FOR A COMPULSORY LICENCE IN UK PATENT SYSTEM

In UK patent system also after the expiration of 3 years of such grant of patents the compulsory license application can be filed to the controller of Patents. The application filed by the interested party should also provide with the grounds for relief. It is the discretion of the controller to whether and on what terms grant a compulsory license.

Compulsory License possess two main regimes such as WTO proprietors and non-WTO proprietors. A WTO proprietor is a national of, or domiciled in, a WTO member country or has a real and effective industrial or commercial establishment in such a country. Most patentees encountered in practice will be WTO proprietors.

d. CAN AN APPLICANT APPLY FOR A COMPULSORY LICENCE IN THE UK IF THE APPLICANT ALREADY HOLDS A LICENCE UNDER THE UK PATENT?

Yes. The Controller may grant a compulsory licence and order the existing licence to be cancelled. Alternatively, the Comptroller may amend the terms of the existing licence.

E. CONCLUSION

If we compare Indian Patent system and UK patent system in terms of compulsory license the European system is wider than the Indian. Most of the countries in Europe follows the provisions of compulsory License effectively and also it imported drugs on the ground of crown use , from the countries where no pharmaceutical patent were granted in the past which prevails till now. Italy being the European country issued a compulsory License for a drug to treat prostate enlargement and baldness for an anti-migraine drug in 2007 after India gained momentum in providing compulsory License in case of generic medicines.

F. COMPULSORY LICENSE IN DEVELOPING AND LEAST DEVELOPED COUNTRIES

Concept of Compulsory License was adopted after the Doha Declaration which came on the effect of TRIPS agreement and Public Health where about 52 countries has worked and issued compulsory Licenses mainly for anti-Aids drugs. The countries such as

- ✓ In the year 2007 in Brazil compulsory license was filed for a drug of anti-Aids.
- ✓ In the year 2006 in Thailand again compulsory license was granted for anti-Aids drugs.
- ✓ In the year 2003 in Malaysia for anti-Aids
- ✓ In the year 2006 in South Africa for Anti Aids Drug
- ✓ In the year 2004 a voluntary license was filed against the threat of compulsory license.
- ✓ In the year 2010 of April that is most recently in Ecuador again for anti-Aids drugs compulsory License was filed...

VIII. JUDICIAL APPROACH-LANDMARK CASES

A. GRANT OF INDIA'S FIRST COMPULSORY LICENSE

a. BAYER CORPORATION V. NATCO PHARMA LIMITED

"Facts: The plaintiff i.e. M/S Natco Pharma Ltd filed an application before the controller for compulsory licence under section 84(1) of the Patents Act 1970 in respect of defendant's i.e. M/s Bayer , USA patented drug called "Sorafenib" also known as "Nexavar" useful in treatment of advanced stage of liver and kidney cancer. Plaintiff argued that reasonable requirements of the public have not been fulfilled by the defendant's patented drug. As per the data generated and published by GLOBOCAN in India the number of Kidney and Liver patients approximate are is 20,000 and 16,000 respectively.

The sales report in India shows that drug has been imported to a very less extent and even the drug is available in only few cities and pharmacies and the sales in India did not exceed USD 32-40 million. If the drug is so highly priced that the ordinary public can't afford it, then it is a fact that the drug is not available to the public on reasonable terms. The plaintiff proposed to sell the drug at Rs.8800/- for one month therapy as compared to Rs.2, 80,428/- which was being charged by defendant at the time of application. Defendant argued that Plaintiff has raised only the ground mentioned under section 84(1) (a) of the Act and has failed to enumerate the grounds under section 84(1) (b) and (c).

The defendant also contended that the provisions of the section 84(6) (iv) have not been satisfied and the application is required to be rejected on this ground alone. Bayer launched this drug in 2006 but was licensed and allowed to import the drug only in 2007.

ISSUES

Whether the reasonable requirements of the public has not been fulfilled by defendant patented drug?

DECISION

The controller of patent consequent to hearing both the get-togethers yielded India's first compulsory allow under Section 84 of the Act to the Plaintiff. The controller insinuated Section 84 of the Patent Act, which says that any individual interested can make an application to the controller for permit of important allow for a patent after 3 years from the date of yield of that patent if any of taking after conditions are satisfied:

- ✓ reasonable requirement of public have not been satisfied
- ✓ it is not available to the public at affordable price
- ✓ The patented invention is not worked in India.

Controller then discussed the competing claims of the Plaintiff and the Defendant according to section 84 of the Act. The case was discussed on the following basis

- ✓ *REASONABLE REQUIREMENTS OF THE PUBLIC*

On the truths the controller found that Bayer did not release its commitment in fulfilling the sensible necessity of the general population as an inconsequential quantum of the medication had been made accessible to people in general in the a long time since concede of the patent.

- ✓ *REASONABLY AFFORDABLE PRICE*

The applicant contended that the drug was excessively priced and unaffordable to the ordinary public. It also contended that Bayer was eligible for a drug tax credit which would have lowered the net cost of investment on the research to Bayer, however, Bayer did not take this opportunity to lower the price of the drug, which proved abuse of its monopolistic rights. The controller did not agree with this proposition stating that reasonable price had to be constructed with reference to the public, without explaining his reasoning. Again in favour of Natco.

- ✓ *PATENTED INVENTION NOT WORKED IN INDIA*

Bayer stated that it did not manufacture the drug in India due to economic reasons and argued that "worked in the territory" could not mean "manufactured In India", based on the interpretations of other sections of the Indian act. However after analysis an interpretation of the act, the controller found that importation could not amount to working of a patent, thus again finding in favour of Natco's interpretation of manufacture".

"The judgment was that the obligatory permit was allowed to the candidate i.e. Natco against which the litigant spoke to the Intellectual Board later on which was rejected. The IPAB moved toward the question from a general wellbeing point of view with regards to one side to life under Article 21 of the Constitution of India, and hailed the significant issues in view of the three-pronged test laid out in segment 84(1) of the Act. In giving the obligatory License to Natco, the controller assessed the way that Bayer had valued Naxavar at`2.85 lakhs for a month's course, while Natco wanted to offer its nonexclusive variant, for just ` 8,900".

B. EMCURE PHARMACEUTICALS V. ROCHE

After the grant of compulsory license in 2012 to the most famous company Natco other pharmaceutical companies also started to file an application in order to receive compulsory license benefit. Therefore Emcure Pharmaceuticals filed an

application for compulsory License in 2012 just after the Natco's Grant in 2012 under the section 92 of the act.

"The applicant was filed for Roche's Drug "Trastuzumab" commonly known as Herceptin. However, the Department of Industrial Policy and Promotion (DIPP) denied the Ministry of Health in proceeding with this application, which had made a request under section 92 of the Patents Act, which allows for the government to file for a license in cases of national emergency". Therefore after analyzing the facts and circumstances of the case the application was rejected in order to protect the main objective of the compulsory License granted under section 92 of the Act.

6.3 M/S BDR Pharmaceuticals International private limited v. M/S Bristol Myers Squibb Co.

In this case M/S BDR Pharmaceuticals is the applicant who filed an application for voluntary License to the defendant M/s Bristol on 2nd febraruary 2012 to manufacture the drug known as "DASATINIB". The applicant asked queries to the applicant and indirectly rejected the application of voluntary License by having continuous communication from both the sides. On 4th march 2013 once again the applicant filed an application for compulsory license under section 84 of the Act and in return the controller of Patents informed the applicant that the case have been made out for making of the act. After such long discussion of the controller and the applicant it was laid down that the application was rejected on the following reasons.

"It was finally held that there was deliberate intent on part of the applicant to enter into any dialogue with the patentee and the exercise of a deliberate choice to only invoke the provisions relating to compulsory licenses without taking the requisite steps laid down by the law, cannot be classified as an 'irregularity in procedure/timeline', which can be waived or condoned or declared to be not applicable. The applicant did not follow the scheme of the law and failed to make out prima facie case for making of an order under Section 87 of the Act. The application for compulsory license was rejected".

C. LEE PHARMA V. ASTRAZENECA

This case is a recent case filed on 29th June, 2015 by Lee pharma who is a Hyderabad based drug manufacturer as applicant against the Astra Zeneca for the patented drug "Saxagliptin"used for the treatment of diabetes Mellitus. The application was filed under section 84(1) of the Act. AstraZeneca was already an assignee to whom the patented drug Saxagliptin was granted by way of deed of assignment in 2007. Lee Pharma contented that the defendant had been importing the patented drug less than a rupee and selling it for Rs. 45 each tablet to the patients who failed to buy such drug to cure its disease. The applicant also contended that the patented drug was not made in India after several efforts by the government on the bad of AstraZeneca which lead to contravention with the Indian laws of the country.

"Patents and Trademark's controller general considered each of the three grounds raised and made the following observations while refusing the application of Lee Pharma under Section 84(1):

- ✓ *REASONABLE REQUIREMENTS OF THE PUBLIC HAD NOT BEEN SATISFIED*

This ground was rejected on the basis that Lee Pharma failed to demonstrate what the reasonable requirement of the public was with respect to Saxagliptin and further failed to prove the comparative requirement of the drug Saxagliptin vis-a-vis other drugs which are also DPP-4 inhibitors.

- ✓ *THE PATENTED INVENTION WAS NOT AVAILABLE TO THE PUBLIC AT A REASONABLY AFFORDABLE PRICE*

This ground was rejected on the basis of comparison of the prices of the various Gliptins available in the Indian market. The CGPTM held that since all the DPP-4 inhibitors were in the same price ranges, it could not be said that the prices of Saxagliptin alone was unaffordable in India as compared to other DPP-4 inhibitors.

- ✓ *THE PATENTED INVENTION HAD NOT BEEN WORKED IN THE TERRITORY OF INDIA*

This ground was rejected on the basis that manufacturing the drug in India is not a precondition to establish working in India and since Lee Pharma had not shown the exact requirement in India, it was difficult to hold whether manufacturing in India was necessary or not."

On 12th August 2015 the Controller General of Patents and Trade Marks issued the decision in the favor of the defendant AstraZeneca.

D. ANALYSIS

The IPA known as Indian Pharmaceutical Association tried many compulsory licenses against the big Pharmaceuticals like Gilead, Cipla, Natco, Mylan, Abbot India and also Dr.Reddy Laboratories for the treatment of Hepatitis C which is a lifelong treatment. Many patients around the world and mainly in India cannot afford to buy such expensive and high rated medicines for their treatment. There have been many deals strucking between the generic manufacturing companies.

Such partnerships leads to increase in profits and cannot be regarded as to the fear of compulsory license on essential drugs. If we compare the filings of compulsory license in each year with respect to various sectors we can find that a slight increase has taken place. The pharma patents filed after 2012 show a little increase in the filings in order to increase the manufacturing of generic medicines.

It has been argued that compulsory license are not obstructing innovation because there has been an increase in the filing of applications for the grant of such license. 2014 also raised the bar by putting the guidelines for examination of biotechnological invention and examination of pharmaceutical inventions. In 2017 computer based inventions are also examined.

Therefore it can be concluded that there can be no decrease in the compulsory license application. in fact there are certain restrictions to the effective functioning of the

patent office such as less number of skilled workers, lack of start-ups, infrastructure. Such change can bring tremendous change in the functioning and meet the expectations to the developed countries.

Compulsory License is a phenomena incorporated in the very first legislation of Patent in the year 1970. The first Indian legislation separately established for the protection of the right conferred on the creator and to prevent from misuse of such invention i.e. Patent in 1970, underwent tremendous changes in order to cope up with the technological advancement and in growth of innovation. Since 1970 till last amendment in 2005 there has been many changes which challenges other developing countries in regard of its working and procedure of granting such Patent as well as issuing compulsory Licenses.

If we study the meaning of Compulsory License in lay man sense it means that the Government issues a license i.e. Right to Use or Sell to the third party other than the patent holder or creator an invention irrespective of being product patent or process patent without the authorization of the patent holder. According to the Act patent holder means patentee is eligible to take exclusive benefit of using and selling its invention without any limitation but keeping in mind the usage and objective of the patent.

The main objective is to benefit the public interests largely and then to acquire economic value of the creation. But such failure to benefit the public leads to the issuance of Compulsory License to the third party. It acts as a preventive measure for the patentees to avoid misuse or abuse of the rights secured.

Before granting the Compulsory license to the third party government on its own complies with the requisites of such grant and also gives opportunity to the Patent holder to prove the abuse of its rights secured. A compulsory licensing application can be entertained only if negotiations towards a voluntary licence have not been within a reasonable time period.

In order to prevent patentees from dragging on voluntary negotiations to the detriment of applicants, the Act caps a 'reasonable' period of negotiations at six months. The commitments of a patentee does not simply include demonstrating that he has attempted certifiable and bonafide endeavors in working the creation economically. The standard which is to be connected ought to be what a sensible individual in the field would do under comparative conditions.

It is to be noted that India is not the only developing Country in the world which provides with the provisions relating to Compulsory License in its domestic legislation.

In any case, such cure has been built up practice in for all intents and purposes every one of the nations on the planet. The main contrast is the minor varieties in their national laws which can be resolved on the premise of conditions and conditions before such concede

Compulsory License is the only area where there have been substantive as well as procedural changes such as Automatic Compulsory License for mailbox Applications. Automatic Compulsory License for mailbox applications granted for pharmaceutical inventions was made in conscience with TRIPS guidelines which aimed to protect and preserve the novelty of Drugs in the developing as well as in least developed countries which failed to grant product patents for drugs and food in 1995.

In 1999 Amendment India adopted a new ground for Compulsory License demanding pharmaceutical inventions to be accepted and put forth in mailbox which is to be examined in 2005. It was the first product patent dealt under the patent Regime. The 1999 Act provides that such grant would issue patent to the companies which made generic drugs as significant investment and marketed throughout world before 2005. Such change required the payment of reasonable royalty to the patent holder but before that how much royalty is reasonable was leading to dispute.

The second most change was incorporated as the section 92A which means Grant of Compulsory License for the export of patented pharmaceutical products in certain exceptional circumstances. This provision allowed the local to produce medicines at a very low cost in order to compensate the public demands at a reasonable price. This helped the countries to import such medicines who lacked the capability of manufacturing such high price drugs.

Inappropriately, it suffered a loss that the provision required the exporter to obtain a compulsory licence from the importing country as well. In the process, the provision failed to cater to those situations where there was no patent in such importing country and no requirement for obtaining a compulsory licence there.

But to compensate the loss the Act of 2005 rectified it by including the exporter can resort to section 92A only where the importing country notified or allowed importation of the pharmaceutical products from India.

If we see the procedural changes then in 2005 the government had added the provision under the chapter XVI of Indian Patent act of Government Use in certain special circumstances. It has widened the scope of government use in some areas and limited its use in certain areas.

Hence now CSIR a reputed science research institution has been excluded from the term Government Undertaking which has been patented extensively and regarded as a private player.

The provision of Compulsory License has an exception known as Bolar Exception which grants the generic companies or producers to start manufacturing a patented drug in small quantities during the data collection for approval by the authority. This exception is applied only when the term of Patent expires and allows it to enter the market.

After the 2005 act India witnessed changes and the efforts of generic manufactures were aided who is working day and night to mitigate the adverse consequences of a pharmaceutical regime. The very basic importance of compulsory License in India are many which are as follows:

- ✓ *GENERIC DRUG INDUSTRY BOOSTED IN INDIA*

India has gained importance as Pharmacy of the third world from the time Compulsory License were given due consideration by allowing a domestic manufacturer to produce drugs. Indian followed such provision rigorously.

✓ *MAKES DRUGS AFFORDABLE*

Generally patented drugs are expensive. This prevents a majority of Indians to access those drugs. Compulsory License enables manufacturing of a drug at fraction of patented cost. This is particularly crucial for lifesaving drugs of HIV, cancer, etc.

✓ *PREVENTS ABUSE OF PATENT RIGHTS*

Compulsory License ensures that pharma do not misuse patent rights for their own commercial advantage.

✓ *BALANCES INNOVATION AND PUBLIC HEALTH NEEDS*

TRIPS recognizes that members have the right to adopt flexibilities to protect public health so long as they are consistent with TRIPS. Compulsory License is one such flexibilities.

Till 2012 no Compulsory License were been issued in India under the amended Patents Act. In September 2007, three applications under section 92A of the Patents Act, 1970 were received for grant of compulsory licence for the manufacture and export of patented drugs to countries which reportedly did not have manufacturing capacity nor had insufficient capacity. The process envisaged under the Act was initiated. However, the applicant subsequently withdrew his applications due to non-recognition of such provision.

In the Indian Patent Act Section 92, the Controller can issue a Compulsory Licence on application only after the Central Government issues a special notification. Under 92A, he is required to act only after either issue of a Compulsory Licence by the importing country or on the basis of a suitable notification issued by that country. It is also known as Category 1 Compulsory License.

Internationally, most compulsory licenses issued in the past so far relate to manufacture or import of pharmaceuticals products and have been issued based on recognition by the Government of either an emergency or the requirement of public use.

In order to understand the main benefits of issuance of compulsory license through government notification are as follows:

✓ *NO WAITING PERIOD*

The new amendment has removed the limitation of time period for application of compulsory License such as when a declaration is made, an application for compulsory license can be filed at any time. The three-year waiting period from the date of grant of patent does not apply as in case of an application for Compulsory license made as earlier.

✓ *NO REQUIREMENT FOR PRIOR NEGOTIATIONS OF VOLUNTARY LICENSE*

As per the normal working of the provision now the controller did not consider if the prior negotiations for grant of voluntary License has been entered by the applicant.

✓ *DISPENSATION OF HEARING*

If the Controller is satisfied that in the cases listed above, including in case of public health crises, including AIDS, HIV, TB, malaria or other epidemics, the Controller shall not follow the procedures for hearing. The Controller is only required to inform the patentee, as soon as may be practicable, of the application for non-application of the hearing procedure.

✓ *ATTEMPT TO ENDEAVOR LOWEST PRICES*

The Controller is additionally required to attempt, while settling the terms and states of the mandatory permit, that the item might be accessible to the general population at the owest costs predictable with the patentees getting a sensible favorable position from their patent rights. In spite of the fact that the typical method is not appropriate, in any case, the choice of the Patent Controller can be tested and alluded to the Appellate Board. The necessity of TRIPS that any Compulsory Licensing choice would be liable to audit does not imply that the genuine utilize ought to be held up till all question are settled. Treks does not oblige Government to give help to patent holders by method for allowing order upon the utilization of a necessary permit. Any restriction to the proposed eminence rate would fulfill 5 October 2014 the prerequisite of the survey of the Compulsory Licensing choice

✓ *USE OF COMPULSORY LICENSE BY THE GOVERNMENT*

The Indian patent law also provides for government use of patents under section 100 of Patents Act, 1970. The Central government or State government or government undertaking may acquire a patented invention for its own use, make, exercise or vend on payment of adequate remuneration or compensation (Sections 99 to 103)..

Whereas, in case of compulsory license for Government use, the patentee retains his patent rights. The patent holder is still the owner of the patented invention even after the issuance of compulsory license for Government use. While in the case of acquisition of the patented invention by the Government for public purpose, the patent owner loses all rights in the patent to the Government. The patentee is to be notified of such acquisition and is entitled to compensation.

The patentee can seek to determine the quantum of compensation by approaching the High Court but cannot challenge such acquisition of its patented invention by the Government. Enlarging the scope of Compulsory License through the Doha Declaration under TRIPS agreement a member country with pharmaceutical manufacturing capacity can resort to Compulsory Licensing to manufacture patented drugs to meet public health needs.

The above grounds are similar to those of Article 31(b) of the TRIPS guidelines who allows member countries to issue compulsory License. According to section 92(3) it explains that the issuance of compulsory License is not for public health problems but includes Immune Deficiency Syndrome, Human Immune Deficiency Virus, Malaria, and other Epidemic's.

This is consistent with Para 5(c) of the Doha Declaration on TRIPS and Public Health which states that public health crises including those related to HIV/AIDS, tuberculosis, malaria and other epidemics can represent a national emergency or other circumstances of extreme urgency. The Patent Act however, does not in any way stipulate that the circumstances justifying issue of a CL are exclusively public health crises. The three circumstances mentioned in above could occur in other sectors also.

Hence we conclude that Indian patent Act was amended several times and led to the inclusion of the Concept Compulsory License for food, medicines, and Pharmaceutical products, Mailbox applications for process and product patents. The 2005 Act has extended the scope of its compulsory License by protecting the manufactured product exported to the countries who lack such manufacturing capacity.

This has widened the scope of application for granting of compulsory License to the third party or the government in order to meet with the requirements of the public at large. Such changes were brought in consideration of the consumer's interest and also to prevent from the abuse of dominance of the patents by the patent holder who exploits its exclusive right entrusted by the right of patents.

There are conditions provided for in the TRIPS Agreement and in the domestic legislation, according to which compulsory licensing of medicines production is possible in cases of emergency and absolute necessity; public non-commercial use; and also when the use is permitted for the purpose of influencing anti-competitive practices.

In general, compulsory licensing of medicines will not be widespread. This is not a license to violate the rights to data exclusivity (during registration) and patent. However, given the intention of the government to reduce the cost of medicines in any way (given the state of the economy, I do not intend to estimate it as positive or negative), despite the interest of innovative companies with their latest developments in the presence in our market, it is possible to initiate compulsory licensing in relation to drugs against HIV \ AIDS, tuberculosis, cancer and others.

Thus, on January 23rd, 2017 changes adopted back in December 2005 came into effect. Article 31 of the TRIPS Agreement came into existence. It provides that the exporting country can issue a compulsory license to produce medicinal products and further export them to the importing country in accordance with certain conditions set out in Section 2 of Article 31 of the Agreement.

IX. CONCLUSION AND SUGGESTIONS

In order to conclude and further suggestions of the concept of Application of Compulsory License under the Indian Patent act 1970 and its applicability after the TRIPS inclusion followed by the Amendment Act 2005 have gained tremendous importance in today's world. Compulsory License has been regarded as the integral part of the patent regime since its origin.

The concept origins from the Indian patent act 1970 under section 84-92 of the Act. It is a system whereby the government authorizes third person or party other than the patent holder to produce or sell the product patent or process patent without the permission of the patentee.

The mechanism was adopted to bring the harmony between the patent holder and the public at large. The main objective was rewarding the inventions and as well as making them available to the public for its benefit. The government tried to balance the rights of the patent holder and availability of the product to the public at reasonable price in order to promote public health and increase the nutrition level in the country.

TRIPS incorporation in 1994 Article 31 along with the DOHA declaration has come with scientific amendments in relation to Compulsory License by extending its scope of allowing compulsory License to the countries who lacks the manufacturing capacity. It also allows them to import the generic drugs if no resources are adequate for such manufacturing. Amendment Act 2005 also allowed automatic Compulsory License for mailbox applications.

The ability of the necessary License searcher to make the item can't likewise be underestimated in all cases. In like manner the legislature of India has exploited these arrangements and have fused suitable arrangements in the patent law in the national interests. It is trusted that the controller may not require to practice these arrangements as the patentees will value the reason for which the patent has been allowed and that he will dedicatedly respect his commitments with generally genuineness.

The provisions were scrutinized and made it parallel to the technological development because it had to achieve the most beneficial advantage of such grant. The advancement of such provision not only provide generic drugs but also makes it easier and convenient for the people at large to use such affordable medicines, food etc.

It has been 30 years from the very first legislation on Compulsory license and there had been no grant of compulsory License. It started in 2012 where India's first compulsory License were granted to Natco Company who manufactured generic medicines at a low cost.

After the first Grant in 2012 it received a due consideration in the eyes of the producers and the interested party leading to filing of 5 applications for Compulsory License till 2017. It gained importance and Public were benefited at large. Such grant in many sectors not only to pharmaceutical leads India from Least developing Country to developed Country. But recently India is regarded as the top Country for the grant of Compulsory License in the world.

Countries like United States, United Kingdom and other Asian countries are also trying to match the pace with India in regard of Compulsory License allowing in different sectors of science and technology. The transition in the Pharmaceutical companies took from process patent regime to product patent regime which can have far reaching effects in the coming years.

Since 2012, five more cases have been dealt by the controller and it sets the tone for coming future situations and will encourage other generic companies to follow this route of manufacturing. It will act as a music to the ears of several patients and other Non-governmental organizations who are

battling pharmaceutical patents and excessive prices for many years till now.

Many have been mystified by the lack of creativity shown by generic companies in availing of the extremely wide compulsory licensing grounds articulated in India's patent regime.

Natco's case is the first case who took the baby step in granting compulsory license and making the way for a giant leap of sorts , and who are subjected to high prices are suggested to bring down the high excessive prices in India.

In fact, given that more than 90% of MNC drugs are imported into India, this order may pave the way for wholesale compulsory licenses to be issued against a wide spectrum of drugs in the near future.

This Judgement has also prompted many countries such as USA, UK and particularly developing countries like India to adopt such provision in order to achieve recognition in the world. We have seen that after 2012, grant of such License have given hopes to the innovators and drug companies to bring about significant changes in its pricing system of drugs which are too costly to be sold and not available to the poor patients in India.

It can be seen that courts having jurisdiction are playing an important role for delivering a judgement in the favor of companies who affords and possess the quality of manufacturing generic drugs for cutting down the difficulties faced by the people who are severely ill.

"There are certain suggestions and recommendations at International level in order to suffice the compulsory Licensing are as follows:

- ✓ The principal recommendation is to discover the method for licensing innovations at a less expensive rates in the creating nations and furthermore to propose them to how to adjust the protected innovation administration in acquiring the further craved outcomes.
- ✓ The second recommendation is to give the creating nations and minimum creating nations to enhance their wellbeing development frameworks keeping in mind the end goal to manage the impacts of full scale TRIPS rules.
- ✓ To make sharpness that Intellectual Property may not really be an inspiration to advancement.
- ✓ with a specific end goal to make the systems of utilization and giving of necessary License quickly to the concerned experts and in addition the part nations of TRIPS.

Such recommendations and guidance should be given a due significance keeping in mind the end goal to fulfill the requests and supply circumstance of the minimum created nations and creating nations who is outfitted with the assembling limit. On the last side, nations require exhortation on sorts of motivation structures for private area that empowers their proceeded with duty in such exercises.

"Certain Policy suggestions for activity at the Indian level that take after from the examination are as recorded underneath:

- ✓ The Indian government needs to put broadly in fortifying existing establishments, for example, nearby rivalry authorization organizations, patent inspectors, an educated legal which is more receptive to the general wellbeing and neighborhood industry needs in a nation like India, and value control components keeping in mind the end goal to elevate access to pharmaceuticals in the neighborhood showcase and other Least Developed Countries.
- ✓ The patent administration joins a few noteworthy TRIPS adaptabilities. Be that as it may, it likewise contains a few arrangements that are interested in various arrangements of translations and hence whether every one of the adaptabilities that are reasonable under the TRIPS Agreement will be utilized by India in everyday practice or not, is still much in the open.
- ✓ Different principles influencing the business, for example, those on information restrictiveness ought to be instituted simply subsequent to mulling over the interests of the generics business and the extent of its effect. In the event that the nonexclusive business in India is checked further, a lot of shoddy supply of solutions at extremely focused costs will be genuinely influenced.
- ✓ The legislature ought to separate from giving a practical regulatory strategy to the usage of Section 92(A) of the Act, make a larger amount of mindfulness among the nearby business on the alternative of 8 necessary authorizing to supply to other minimum created nations. This could bring about a more favorable state of mind among the organizations to manage demands from other slightest created nations in future.
- ✓ The legislature ought to, in a purposeful exertion with the business, arrange courses in which to diminish bottlenecks to pharmaceutical R&D in the nearby Indian setting. These will be exceptionally useful to help the business to devise and actualize systems for survival.
- ✓ The legislature ought to fortify its exercises as far as distinguishing key ranges where there is potential (for instance, clinical research) and put resources into advancement of these offices deliberately.
- ✓ Advancement of R&D into maladies of the creating scene, as the overview goes ahead to show, will remain an open decent issue, regardless of the limits in the pharmaceutical segments in creating nations. The administration of India (either independently or in a joint effort with different governments in creating nations) ought to start more open R&D programs that use the qualities of the Indian business to discover cures for disregarded illnesses".

Issues which will be raised in future and need to be given due importance

- ✓ The first issue is that the procedures, considerations, time limits specified for compulsory License should be clear and available to all parties.
- ✓ The application for compulsory License should be made clear and with no ambiguity that it is made for public health and for chronic diseases. Like asthma.
- ✓ The spirit of the compulsory license is a special reason of National emergency, extreme urgency and public non-commercial use to be defined simply in order to comply with the provisions.
- ✓ Government channels only distributes the medicines as specified under category 1 that they should be provided free of cost to patients and have to be differentiated packaging to prevent misuse.

- ✓ No issuance on the basis of anti-competition law should be treated as the spirit of compulsory license. In order to safeguard the public health compulsory license is an extreme measure.
- ✓ The main issue is that it should that the medicines working should be a criteria of patent protection and not where and how it is made.
- ✓ Royalty should be negotiated with the patent holder and the compulsory license should be invoked only on the consultation of patent holder.
- ✓ The Government must balance the need to increase access to medicines without denying the innovator the right to recover the cost of investment in the drug discovery.
- ✓ According to Indian laws, patent applicants have to be disclosed to achieve an invention "fully and particularly". Disappointment to do so can limit the success of the patent being granted. Therefore disclosure do not obstruct compulsory License.
- ✓ If any desired steps are taken to hamper the activities of big multinational companies in India or other developing countries will only hurt the assessment to the global resources technology and new drugs.
- ✓ Protection given to pharmaceutical industry, food and other process patents will make the growth smother in the coming years in order to achieve the great success in manufacturing and making available the lifesaving drugs in India as well as other countries who lack manufacturing capacity.

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