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COMPULSORY LICENSING OF PHARMACEUTICAL PATENTS IN INDIA: A RESEARCH STUDY

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ABSTRACT

Patents provide monopoly rights for the patent owners over their new, inventive and innovations. Patents are granted with an expectation that the patent owners would work the patented inventions without undue delay on the commercial scale to the fullest extent as practically possible. But in some cases the patent rights may be subject to abuse by the patent owner. To prevent such abuse provisions of compulsory license are provided under the patent law. However, compulsory licensing provisions in India have been under criticism particularly at the international front. This paper examines and compares provisions for compulsory licensing in India with the relevant provision in U.S., Europe and China. The paper also takes into account important case laws, and empirical data collected on the issue through a questionnaire based survey. The paper concludes by proposing measures to strengthen the compulsory licensing provisions in India.

KEY WORDS: Patent, Patents Act, patent abuse, compulsory license.

INTRODUCTION

Patent is an exclusive right granted to a person who invents a new and useful product or process. Patent provides a monopoly right for 20 years to the patent holder to prevent others from exploiting the invention. Patents reward the inventors for their skills, efforts and resources to encourage innovation.[1] Patent is granted from the government in lieu of full disclosure of the invention by the inventor. Without the presence of a patent system the inventor will not be encouraged to disclose his invention and may prefer to keep it as a trade secret, which may lead to sluggishness in the research and development of new technologies.[2]

Research in the field of drugs & pharmaceutical is very expensive, time consuming and unpredictable in nature. Innovator pharmaceutical companies therefore try to get their research patented in order to prevent market entry of their competitor generic drug companies. However, sometimes patent rights may be subject to abuse by the patent holder.[3] Pharmaceutical company holding the patent right may not commercialize the patented drug in the country, or may not provide the drug in sufficient quantity to meet the requirements of the public, or may price the drug exorbitantly high. As drugs are an essential commodity, such abusive or monopolistic practice by the companies can severely aggravate the sufferings of the patients, especially of the poor ones.

To prevent such abuse of the patent rights, provisions of compulsory license are included in the patent laws. Compulsory licensing is defined by the World Trade Organization (WTO) as a practice in which the government allows someone else to produce the patented product or use the patented process without the consent of the patent owner. It is one of the flexibilities on patent protection included in the TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement.[4]

Compulsory licence is an involuntary contract between a willing buyer and an unwilling seller imposed or enforced by the law.[5] Compulsory licence authorizes a third party to make, use, or sell a patented invention without the consent of the patent holder. In India grant of patent rights and compulsory license are governed by the Patents Act, 1970.

RELEVANCE AND OBJECTIVES OF THE STUDY

In 2012, India issued its first compulsory license for patents. The compulsory license was issued to Natco Pharma Ltd. in patent number 215758 granted to M/s Bayer Corporation. This decision of the Indian government provoked intense debate at the international

front, particularly by the multinational pharmaceutical companies, and the U.S. government and its representatives. It was argued that India's compulsory licensing provisions violate the TRIPS agreement.[6]

In 2013, 170 Members of U.S. Congress sent a letter to President Barack Obama criticizing India for its intellectual property climate. The members specifically criticized India's compulsory licensing provisions.[7]

In 2014, reports issued by the "United States International Trade Commission" and the "Office of the United States Trade Representative"[8-9], criticized India's compulsory licensing provisions by stating that Indian government has promoted compulsory licensing in its "National Manufacturing Policy" as a mechanism for effectuate technology transfer in certain sectors, which indicates that the government is using compulsory licensing merely as a tool to achieve its industrial policy goals rather than towards protecting public health in the country.

Looking at the growing concerns and apprehensions raised over compulsory licensing provisions in India, this study was aimed to examine India's position on compulsory licensing, identify the areas of improvement and suggest measures to strengthen provisions on compulsory license in India.

METHODOLOGY

Compulsory license provisions in India were reviewed and compared with the relevant provisions of TRIPS, U.S., Europe and China. Further, important case laws were reviewed and data was collected through a research questionnaire. Based on the comparative study, review of the case laws and analysis of the questionnaire data, suggestions for strengthening the compulsory license provisions in India are proposed.

RESULTS AND DISCUSSION

Compulsory licensing provisions under TRIPS agreement

TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement administered by WTO (World Trade Organization) took effect in January, 1995. TRIPS has set the intellectual property rules for the multilateral trading system among the countries. It has established minimum standards/ requirements for intellectual property protection that are to be adapted by all its member countries. However, TRIPS agreement incorporates certain "flexibilities" (TRIPS flexibilities) that permit developing and least-developed countries to use TRIPS-compatible norms in a manner that enables them to pursue their own public policies e.g. protection of public health and promotion of access to medicines.[10]

The term "compulsory licensing" does not appear as such in the TRIPS agreement, however compulsory licensing is covered under Article 31 of the agreement. Compulsory licensing is a part of TRIPS flexibilities that aims to strike a balance between promoting access to existing drugs and promoting research and development into new drugs.[11]

The salient requirements for compulsory licensing (other use without authorization of the right holder) under the TRIPS Article 31 are:

1. Grant on individual merits: Each application for the grant of compulsory license shall be considered on its individual merits [Article 31(a)];
2. Prior efforts of the applicant to obtain a voluntary license is necessary: Compulsory license may only be permitted if, prior to making the application the applicant has already made efforts to obtain a voluntary license from the patentee on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time [Article 31(b)];
3. Waiver of the prior efforts requirement: The requirement of making prior efforts to obtain a voluntary license by the applicant may be waived in the case of a national emergency/ other circumstances of extreme urgency/ in cases of public non-commercial use. However, the patentee shall be notified as soon as practicable about waiving of such requirement [Article 31(b)];
4. License in the case of semi-conductor technology: In the case of semi-conductor technology, the compulsory license shall be issued only for public non-commercial use or to remedy an anti-competitive trade practice [Article 31(c)];
5. Non-exclusive basis: The compulsory license shall be granted on non-exclusive basis [Article 31(d)];
6. Non-assignable: Right of the licensee is non-assignable [Article 31(e)];
7. Predominant use for the domestic market: The compulsory licence shall be granted with a predominant purpose of supply in the domestic market of the country granting the license [Article 31(f)];
8. Termination of the compulsory licence: The compulsory license may be terminated upon a request made by the patentee to the competent authority, if and when the circumstances based upon which the compulsory license was granted cease to exist and are unlikely to recur. Such termination shall be subject to the adequate protection of the legitimate interest of the compulsory license holder [Article 31(g)];
9. Adequate remuneration to the patentee: The patentee shall be paid adequate remuneration, taking into account the economic value of the compulsory license granted [Article 31(h)];
10. Decision subject to judicial review: The legal validity of any decision relating to the grant of compulsory license and/or payment to the patent holder is subject to judicial review in the country granting the compulsory license [Article 31(i) and (j)];

11. Special considerations in the case of anti-competitive practices: If the patentee is found engaged in any anti-competitive practice then the member country is not obliged to apply the conditions of "prior efforts of the applicant necessary to obtain a voluntary license" and "predominant use for the domestic market" [Article 31(k)];
12. Licensing of related patents: Holder of a patent ("the second patent") can apply for the grant of a compulsory license with respect to another patent ("the first patent"), where the second patent cannot be exploited without infringing the first patent, subject to the conditions that (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent; (ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent [Article 31(l)].

The Doha Declaration on TRIPS and Public Health: WTO's fourth ministerial conference was held in Doha, Qatar, on 14 November, 2001. In this conference the WTO members adopted the "Declaration on the TRIPS Agreement and Public Health".**[12]**

Through Doha Declaration the WTO members recognized and affirmed:

a) the need to address public health problems including HIV/AIDS, tuberculosis, malaria and other epidemics afflicting many developing and least developed countries;
b) that the TRIPS Agreement does not and should not prevent the members from taking measures to protect public health;
c) that the agreement should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and to promote access to medicines for all;
d) that each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted;
e) that each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency;
f) that public health crises, including HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency;
g) that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS agreement, and instructed the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002 ("Paragraph 6" of the declaration).

The "Paragraph 6" of the declaration recognized that the TRIPS agreement limited the effective use of compulsory licensing in those countries with insufficient or no manufacturing capacities in the pharmaceutical sector, since originally the TRIPS Article 31(f) provided that compulsory licensing could only be used predominantly for the purposes of supply of the domestic market of the country in which the licence was issued.**[13]**

In 2003, the General Council of the WTO adopted the decision on implementation of Paragraph 6 of the Doha Declaration on the TRIPS and Public Health, which finally resulted in the form of Protocol to amend TRIPS Agreement in 2005.**[14]** The "Paragraph 6" decision amended the Article 31(f) obligation and allowed the member countries to issue compulsory license for export of patented pharmaceutical products to the countries with insufficient or no manufacturing capacities in this sector.

Compulsory licensing provisions in the U.S.

There are no provisions on compulsory licensing provided in the U.S. patent law. However, there are other domestic laws in the U.S. which allow the use of patented inventions by others without the consent of the patentee, just similar to compulsory licensing.**[15]** 28 U.S.C. 1498(a) permits the U.S. government to take a compulsory license and use or manufacture an invention described in a U.S. patent without the consent of the patentee. The patentee can claim for the recovery of reasonable compensation for such use or manufacture from the government in the United States Court of Federal Claims.**[16]** In 2001, in the wake of several mail anthrax cases, the U.S. government threatened the pharmaceutical company Bayer to issue compulsory license under 28 U.S.C. 1498(a) on its patented drug Ciproflaxin. Bayer subsequently dropped price of the drug drastically.**[17]**

Compulsory licence is also available in the anti-trust cases under the Sherman Antitrust Act. In an anti-trust case "*United States v. Glaxo Group"*, the Supreme Court held that Glaxo Group and Imperial Chemical Industries Ltd. (ICI) were engaged in restraining trade of the patented anti-fungal drug griseofulvin. Glaxo and ICI each owned patents covering various aspects of griseofulvin. They pooled their patents on griseofulvin i.e. cross-licensed patents one another, subject to express licensing restrictions that the drug must not be resold in the bulk form. The purpose of this restriction was to keep the drug out of the hands of small generic companies that might act as price-cutters. Consequently, the court ordered mandatory sales and compulsory licensing against Glaxo and ICI.[18]

In the case of patent infringement, the patentee may seek for injunctive relief through the U.S. court. However, as per the Supreme Court's decision in *eBay Inc. v.*

MercExchange, in the case of non-working of the patent, the U.S. courts may deny injunctive relief to the patentee allowing compulsory license to the alleged infringer. In such case the patentee shall be entitled to receive damages in the form of reasonable royalties.[19]

Under the Bayh-Dole Act, the government contractors (e.g. universities, small business or non-profit institutions) may acquire patents on inventions that they have made using the government funding. The Act allows the government to issue compulsory license on such patents owned by the contractors, if the contractor fails to work the invention or fails to satisfy the health and safety needs of the consumers.[20]

Compulsory license may also be issued under the Clean Air Act, 1970 (42 U.S.C. §§ 7401-7626); the Atomic Energy Act, 1954 (42 U.S.C. § 2183); and the Plant Variety Protection Act, 1970 (7 U.S.C. § 2404).[21]

Compulsory licensing provisions in Europe

In Europe patent grant is dealt under the domestic patent legislation of each member country as well as via a single, harmonised procedure at the European Patent Office (EPO) under the European Patent Convention (EPC).

As per the Doha Declaration, European Regulation (EC) No. 816/2006 has prescribed provisions on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.[22]

This regulation has set the following main requirements for the grant of compulsory license in Europe:

a) The applicant shall prove that he made efforts to obtain voluntary authorisation from the patentee and that such efforts have not been successful within a period of thirty days before submitting the application.
b) Above requirement shall not apply in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.
c) The licence granted shall be non-assignable.
d) The amount of the product manufactured under the compulsory licence shall not exceed to the requirement of the importing country (ies) cited in the application.
e) The product made or imported under the compulsory licence shall not be sold or put on the market in any country other than that cited in the application.
f) Products manufactured under the licence shall be clearly identified, through specific labelling or marking, as being produced pursuant to this Regulation.
g) Before shipment to the importing country the licensee shall post on a website - name of the importing country (ies); the quantity of the product(s) being supplied; the distinguishing features of the product(s). The website address shall be communicated to the competent authority.
h) The competent authority may access to books and records kept by the licensee, to check whether the terms of the licence, have been met.
i) The licensee shall pay adequate remuneration to the patentee. In the situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use, the remuneration shall be a maximum of 4% of the total price paid by the importing country. In all other cases, the remuneration shall be determined taking into account the economic value of the product and humanitarian or non-commercial grounds relating to the issue of the licence.
j) The competent authority may refuse an application if any of the conditions essential for the grant of the license as prescribed under this regulation are not met. However, before refusing the application, the competent authority shall give the applicant an opportunity to rectify the application and to be heard.
k) If at any time after the issue of a compulsory licence, the competent authority found that the licence conditions are not being met by the licensee, the licence may be terminated. Such termination shall be subject to adequate protection of the legitimate interests of the licensee.

Directive 98/44/EC, on the legal protection of biotechnological inventions has provided for mandatory compulsory cross-licenses of certain biotechnology inventions. Under this directive, where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for the invention protected by the patent. If such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety. Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for the plant variety protected by that right. If such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention.[23]

Compulsory licensing provisions in China

Provisions related to compulsory licensing are prescribed under the Chapter VI (Article 48-58) of the Chinese patent law. Further, in March, 2012 China State Intellectual Property Office (SIPO) issued "Measures for Compulsory Licensing of Patent Implementation" via the office order No.64. These measures were formulated to standardize the procedures relating with grant, fees adjudication and termination of compulsory licenses of patents.[24-25]

Main provisions for compulsory licensing under the Chinese patent law are:

a) SIPO can grant a compulsory license upon application made by an applicant, three years after the date of patent grant and four years after the date of patent application submission, on the grounds that - (a) the patentee, without legitimate reasons, fails to exploit/ fully exploit the patent; or (b) the patentee's exercise of the patent right has been confirmed as monopoly and its negative impact on competition needs to be eliminated or reduced (Article 48).
b) SIPO can grant a compulsory license, if national emergency or any extraordinary state of affairs occurs, or it is required in the public interest (Article 49).
c) For the benefit of public health, compulsory license may be granted for the manufacture of a drug and for the export to the countries that conform to the provisions of the relevant international treaties e.g. TRIPS or Doha Declaration (Article 50).
d) In the case of related patents, where exploitation of a patent "the second patent" relies on the exploitation of another patent "the first patent", and invention described in the second patent represents a major technological advancement of remarkable economic significance, SIPO may, upon application made by the holder of the second patent grant him a compulsory license to exploit the invention described in the first patent. In such condition, holder of the first patent shall also be eligible to acquire a license to exploit the invention described in the second patent (Article 51).
e) In the case of semi-conductor technology, the compulsory license shall be issued only for purpose of public interests or to remedy monopoly and its negative impact on competition (Article 52);
f) Except in the cases of monopolistic practice by the patentee or license granted for the export of drug(s), compulsory license shall mainly be exercised for the supply to the domestic market (Article 53).
g) For an application made under the above clauses (i) or (iv), the applicant shall provide evidence to show that before making the application he has, under reasonable terms, made efforts to obtain patentee's permission to exploit the patent, but fails to obtain such permission within a reasonable period of time (Article 54).
h) Upon request made by the patentee, if it is found that the reasons justifying the grant of the compulsory license cease to exist and are unlikely to recur, the compulsory license shall be terminated (Article 55).
i) Compulsory license shall be granted on non-exclusive basis (Article 56).
j) The license holder shall pay reasonable royalties to the patentee (Article 57).
k) A patentee who is dissatisfied with the decision made by SIPO on granting of the compulsory license or regarding the royalties, he may take legal action before the people's court within three months from the date of receipt of the notification of the decision (Article 58).

The "Measures for Compulsory Licensing of Patent Implementation, 2012" has prescribed detailed guidelines on various aspects relating to the grant and termination of compulsory license in China. The guideline consists of the following chapters:

- General provisions
- Submission and acceptance of petitions for compulsory licensing
- Examination and determination of petitions for compulsory licensing
- Examination and adjudication of fee adjudication requests of a compulsory license
- Examination and decision regarding terminating the compulsory license
- Supplementary provisions

Although China has not yet issued any compulsory license *per se*, however in 2005, amid the bird flu outbreak, China threatened Roche Pharma to issue compulsory license of its patented drug Oseltamivir (Tamiflu). As a result, Roche entered into voluntary agreement with two generic companies to ensure sufficient supply of the drug to meet the public requirements in China.[26]

Compulsory licensing provisions in India

Provisions related to the grant of compulsory license in India are prescribed under Sections 82-94 (Chapter XVI) of the Patents Act, 1970, and Rules 96-102 (Chapter XIII) of the Patents Rules, 2003.[27] The Controller of Patents can issue compulsory license under following situations - compulsory license u/s 84; licensing of related patents u/s 91; special provision for compulsory licences on notifications by central government u/s 92; and compulsory licence for export of patented pharmaceutical products in certain exceptional circumstances u/s 92A.

(i) Compulsory license u/s 84

A compulsory license may be granted to an interested person after expiry of three years from the date of patent grant on any of the following grounds that the -

(a) reasonable requirements of the public with respect to the patented invention have not been satisfied; or
(b) patented invention is not available to the public at a reasonably affordable price; or
(c) patented invention is not worked in the territory of India.

Section 84(7) of the Patents Act identifies a list of circumstances, if any of which occurs, the reasonable requirements of the public shall be treated not to have been satisfied. These circumstances include - (a) the patentee refuses to give license and that results in harming the trade, industry or commercial activities in India; or demand for the patented article not being met;

or market for export of the patented article not being developed (b) the patentee imposes unreasonable conditions upon the grant of licences which are prejudice to the development of trade and industry in India (c) the patentee imposes conditions of exclusive grant back, prevention to challenge the validity of patent or coercive package licensing (d) the patented invention is not worked in India on commercial scale to an adequate/ fullest extent in a reasonably practicable way; (e) working of the invention on a commercial scale in India is prevented due to importation of the patented article from abroad.[28]

The Controller while determining a "reasonably affordable price" may take into account various factors such as the purchasing power of Indian public/ end-user(s) of the patented product, cost of the production, availability and affordability of any substitute of the product etc. [29]

General principles applicable to "working of patented inventions" are prescribed under section 83 of the Patents Act. It is one of the general principles that the patents are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article in India [section 83(b)]. Therefore, for a patented invention to be treated as "worked in the territory of India" the invention shall be manufactured to a reasonable extent in India.[30] Further, the patentee must not abuse his patent rights by adopting any anti-competitive activity, or resort to practices which unreasonably restrain trade/ adversely affect the international transfer of technology [section 83(f)].[31]

Terms and conditions of compulsory licences: General terms and conditions for the grant of compulsory licences u/s 84 are.[32]

a) patentee gets reasonable amount of royalty/ remuneration with respect to the nature of the invention, expenditure incurred by the patentee in developing/ making the invention and obtaining/ keeping in force the patent and other relevant factors [section 90(1)(i)];
b) patented invention is worked to the fullest extent by the licensee with reasonable profit to him [section 90(1)(ii)];
c) patented articles are made available to the public at reasonably affordable prices [section 90(1)(iii)];
d) licence is granted on non-exclusive basis [section 90(1)(iv)];
e) right of the licensee is non-assignable [section 90(1)(v)];
f) licence is granted for the balance term of the patent [section 90(1)(vi)];
g) licence is granted with a predominant purpose of supply in the Indian market, however the licensee may also export the patented product, if need be in accordance with the section 84(7)(a)(iii) of meeting reasonable requirements of the public [section 90(1)(vii)];
h) in the case of semi-conductor technology, the licence granted is to work the invention for public non-commercial use [section 90(1)(viii)];
i) in the case of any anti-competitive practice by the patentee, the licensee is permitted to export the patented product [section 90(1)(ix)];
j) the licensee is not authorized in general to import the patented product or product made by the patented process where such importation would constitute an infringement of the rights of the patentee, however if it is necessary in the public interest, controller may authorise (on the basis of the direction given by the central government) the licensee to import the patented product or product made by the patented process from abroad, subject to the conditions of royalty payable to the patentee, the quantum of import, the sale price of the imported article and the period of importation etc. [section 90(2)&(3)].

Procedure for grant of compulsory license u/s 84[33,34,35]: An application for the grant of a compulsory license shall be made only when before making the application the applicant has made efforts to obtain a voluntary licence from the patentee on reasonable terms and conditions, and such efforts were not successful within a reasonable period (six months). However, this condition shall not be applicable in case of national emergency or in circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anti-competitive practices adopted by the patentee [section 84(6)(iv)].

The application for the grant of a compulsory license shall contain a statement mentioning the nature of the applicant's interest, the facts upon which the application is based and other relevant particulars. Upon consideration of an application, if the controller is satisfied that a prima facie case has been made for the issue of a compulsory license, he directs the applicant to serve copies of the application upon the patentee, and shall publish the application in the official journal. The patentee within two months from the date of the publication of the application may give to the controller a notice of opposition containing a statement of the grounds on which the application is opposed. The controller then notifies the applicant, and gives to the applicant and the patentee an opportunity to be heard before deciding the case.

While considering the application for the grant of a compulsory license, the controller shall take into account [under section 84(6)(i-iii)] - nature of the invention, time which has elapsed since the grant of the patent, measures already taken by the patentee or any licensee to make full use of the invention, ability of the applicant to work the invention to the public advantage and the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted.

Termination of compulsory licence[36]

Upon an application made by the patentee, the compulsory licence may be terminated by the controller, if the controller finds that circumstances based upon which the license was granted no longer exist and such circumstances are unlikely to recur in future. The holder of the compulsory licence can object to such termination. Before making any final decision on the termination of the compulsory licence, the controller shall take into account that the interest of the holder of the compulsory licence is not unduly prejudiced (section 94).

(ii) Licensing of related patents u/s 91

After the grant of a patent ("the first patent"), any person who has the right to work any other patented invention ("the second patent") either as the patentee or as a licensee, where the second patent cannot be exploited without infringing the first patent, may apply to the Controller for the grant of a compulsory licence of the first patent, subject to the conditions that (i) the applicant is able and willing to grant a licence in respect of the second patent to the patentee of the first patent on reasonable terms; and (ii) that the invention described in the second patent has made a substantial contribution to the establishment/ development of commercial or industrial activities in India. General procedure and terms and conditions of compulsory licences u/s 84 shall also be applicable under this provision.[37]

(iii) Special provision for compulsory licences on notifications by Central Government u/s 92

Compulsory license may be issued in the circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, including public health crises. If any of such situations arises, the central government shall make a declaration in the official gazette for the grant of compulsory licence by the controller with respect to any patent in force.[38]

After the notification is issued, the controller shall issue a compulsory licence after following the general terms and conditions of compulsory license specified under section 90 and normal procedure such as notice to the patentee, hearing to objections, etc. specified under section 87. The controller is also required to ensure that the articles are manufactured in India and made available to the public at the lowest price consistent with the patentees deriving a reasonable advantage from their patent rights.[39] In the case of any public health crises, relating to Acquired Immuno Deficiency Syndrome (AIDS), Human Immunodeficiency Virus, tuberculosis, malaria or other epidemics, the controller is exempted to follow any procedure specified in section 87. In such cases, however the controller shall as soon as may be practicable inform the patentee of the non-application of the procedure.

(iv) Compulsory licence for export of patented pharmaceutical products in certain exceptional circumstances u/s 92A[40]

This provision allows manufacturing and export of pharmaceutical products to countries with insufficient or no manufacturing capabilities for the concerned pharmaceutical product to address public health problems. The compulsory licence can be issued only if such country has granted a compulsory licence to the applicant (if the product is patented in such county) or allowed importation of the patented pharmaceutical products from India (if the product is not patented in such county).

Pharmaceutical products here mean, any patented product, or product manufactured through a patented process, to address public health problems. It includes ingredients necessary for their manufacture and diagnostic kits required for their use.

Cases on compulsory licensing in India

(a) *Natco v. Bayer* case

On March 9, 2012, the Controller of Patents issued the first compulsory license for patents in India. The compulsory license was issued to Natco Pharma Ltd. in patent number 215758 granted to M/s Bayer Corporation.[41] This patent relates to drug Sorafenib tosylate sold under the brand name Nexavar by Bayer. Nexavar is indicated in Renal Cell Carcinoma - RCC (kidney cancer) and Hepatocellular Carcinoma - HCC (liver cancer). The Controller granted the compulsory license to Natco to manufacture and sell a generic version of Nexavar and pay Bayer a royalty of at the rate of 6% of its net sales. Further, Natco cannot charge more than Rs. 8800/- for a monthly dose of 120 tablets of the drug.

The decision of the Controller was based on section 84 of the Patents Act. The Controller found that the reasonable requirements of the public with respect to the patented invention had not been satisfied, since only 2% of the total kidney and liver cancer patients were able to access the Bayer's drug. The Controller determined that the patented invention was not available to the public at a reasonably affordable price, because Bayer was charging about Rs. 2.8 lakhs for a therapy of one month of the drug. The Controller also found that the patented invention was not worked in the territory of India since Bayer was not manufacturing the product in India rather it was importing it from outside India.

Bayer appealed to the Intellectual Property Appellate Board (IPAB). In March 2013, IPAB upheld the Controller's decision but increased the royalty payable to Natco from 6% to 7%. On the issue of working a patent in India, IPAB took a contrary view stating that the requirement of working of a patent could be satisfied by importing the patented product if the patentee could satisfy that the patented product could not be manufactured in India. Therefore, manufacture in India

was not an absolute necessity to satisfy the working requirements. Bayer then filed a writ petition in the Bombay High Court, challenging the IPAB order. In July 2014, The Bombay High court dismissed the writ petition upholding the order of the Controller and the IPAB.[42] Subsequently Bayer filed a Special Leave Petition (SLP) in the Supreme Court against the Bombay High Court's decision. However, in December 2014, the Supreme Court dismissed Bayer's SLP upholding the compulsory license issued to Natco and concluding the legal proceedings on the case.[43]

(b) Other cases

Following the *Natco v. Bayer* case, two more applications were filed in India for the issue of compulsory licenses. However, both the applications were rejected by the Controller of Patents. Brief details of these applications are outlined below.

In March 2013, BDR Pharmaceuticals filed an application for compulsory licence to make generic version of anti-cancer drug Dasatinib patented by Bristol-Myers Squibb in India. The Controller rejected BDR's application stating that before making the application for compulsory licence the applicant didn't make reasonable efforts to convince the patentee for grant of a voluntary license and therefore applicant failed to make out a prima facie case for the issue of a compulsory license under the Patents Act.[44]

In June 2015, Lee Pharma filed an application for seeking the grant of a compulsory licence for manufacturing and selling the drug Saxagliptin used in the treatment of type-II diabetes mellitus. Saxagliptin is patented by Bristol Myers Squibb and marketed by AstraZeneca in India. The Controller rejected the application mentioning that applicant failed to satisfy regarding any of the grounds as specified in the section 84(1) of the Act.[45]

Whether the compulsory licensing provisions in India are TRIPS compliant?

To examine whether India has complied with the TRIPS requirements for compulsory licensing, provisions for compulsory licensing under TRIPS agreement and Indian Patents Act were compared. Results of the comparison are presented in the table 1.

Table 1: Comparison of the compulsory licensing provisions under TRIPS agreement and Indian Patents Act

S. No.	TRIPS requirements for compulsory licensing	Relevant section in the Indian Patents Act	TRIPS compliance by India (Yes/ No)
1	Grant of compulsory license on individual merits [Article 31(a)]	Section 84(6)(i-iii)	Yes
2	Prior efforts of the applicant to obtain a voluntary license is necessary [Article 31(b)]	Section 84(6)(iv)	Yes
3	Waiver of the prior efforts requirement [Article 31(b)]	Section 84(6)(iv)	Yes
4	License in the case of semi-conductor technology [Article 31(c)]	Section 90(1)(viii)	Yes
5	Non-exclusive basis [Article 31(d)]	Section 90(1)(iv)	Yes
6	Non-assignable [Article 31(e)]	Section 90(1)(v)];	Yes
7	Predominant use for the domestic market [Article 31(f)]	Section 90(1)(vii)	Yes
8	Termination of the compulsory licence [Article 31(g)]	Section 94	Yes
9	Adequate remuneration to the patentee [Article 31(h)]	Section 90(1)(i)	Yes
10	Decision on compulsory license subject to judicial review [Article 31(i)&(j)]	Section 117A (Decision of the Controller appealable at IPAB)	Yes
11	Special considerations in the case of anti-competitive practices [Article 31(k)]	Sections 84(6)(iv); 90(1)(ix)	Yes
12	Licensing of related patents [Article 31(l)]	Section 91	Yes
13	Export of patented pharmaceutical products (Paragraph 6 decision of the Doha Declaration)	Section 92A	Yes

In the above comparison, it was found that all the requirements for compulsory licensing prescribed under the TRIPS agreement are complied with in the Indian Patents Act. Hence, it was concluded that the compulsory licensing provisions under the Indian Patents Act are fully TRIPS compliant.

Comparison of compulsory licensing provisions in U.S., Europe, China and India

Provisions for compulsory licensing in India were compared with the relevant provisions in U.S., Europe and China.

Comparison of compulsory licensing provisions in the U.S. and India is provided in the table 2.

Table 2: Comparison of compulsory licensing provisions in the U.S. and India

S. No.	Ground for compulsory license (CL)	Provision in the U.S. law	Provision in Indian Patents Act
1	Use of patented invention by or for the government	28 U.S.C. 1498(a)	(1) Sec. 92: CL on notifications by central government (2) Sec. 99-103: Use of invention for purposes of government
2	Anti- competitive/ anti-trust practice by the patentee	Sherman Antitrust Act	Sect. 83(f): Anti- competitive practice is a ground for the issue of CL
3	Non-working of the patent by the patentee	Denial of injunctive relief as per the Supreme Court's decision in *eBay Inc. v. MercExchange*	Sec. 84(1)(c): Non-working of the patent is a ground for the issue of CL
4	Non-working of patents acquired under government funded projects	Bayh-Dole Act	No similar Act

Although TRIPS flexibilities for compulsory license have not been adopted in the U.S. patent law, still provisions similar to compulsory licensing are provided in other domestic laws in the U.S. Both U.S and India may grant compulsory license on the grounds of government use, anti- competitive practice and non-working of the patent. Further, in the U.S. compulsory license may also be granted under Bayh-Dole Act, whereas this type of provision is currently not available in India.

Comparison of compulsory licensing provisions in Europe and India is provided in the table 3.

Table 3: Comparison of compulsory licensing provisions in Europe and India

S. No.	Ground for compulsory license (CL)	Provision in the European Regulation	Provision in Indian Patents Act
1	Export of patented pharmaceutical products under paragraph 6 decision of the Doha Declaration	Regulation (EC) No 816/2006	Section 92A
2	Mandatory cross-licensing between the owners of patented biotechnology inventions and registered plant variety	Directive 98/44/EC	No similar provision

Provisions for the export of patented pharmaceutical products as per the Doha Declaration have been adopted both under European and Indian regulations. Provisions for the mandatory cross-licensing between the owners of biotechnology patents and registered plant varieties are currently not available in India.

Comparison of compulsory licensing provisions in China and India is provided in the table 4.

Table 4: Comparison of compulsory licensing provisions in China and India

S. No.	Ground/ parameter for compulsory license (CL)	Provision in the Chinese Patent Law	Provision in Indian Patents Act
1	Non-working of the patent by the patentee	Article 48	Sec. 84(1)(c)
2	Anti- competitive practice by the patentee	Article 48	Sect. 83(f)
3	Circumstances of national emergency or extreme urgency	Article 49	Sec. 92
4	Public health crises	Article 50	Sec. 92
5	Export of patented drugs	Article 50	Section 92A
6	Licensing of related patents	Article 51	Section 91

7	Predominant use for the domestic market	Article 53	Section 90(1)(vii)
8	Prior efforts of the applicant to obtain a voluntary license is necessary	Article 54	Section 84(6)(iv)
9	Termination of the compulsory licence	Article 55	Section 94
10	Non-exclusive basis	Article 56	Section 90(1)(iv)
11	Adequate remuneration to the patentee	Article 57	Section 90(1)(i)
12	Decision on compulsory license subject to judicial review	Article 58	Section 117A
13	Detailed guidelines on CL	Measures for Compulsory Licensing of Patent Implementation, 2012	No similar guidelines

Both China and India have adopted compulsory license provisions based on the grounds specified under TRIPS agreement (see table 1). China has prescribed detailed guidelines on compulsory license. No similar guidelines are available in the India regulation.

Collection and analysis of the questionnaire data

A questionnaire was formulated comprising various questions/ concerns raised over the current patenting system in India at national and international fronts in the recent time. Responses were collected online as well as in-person from professionals and experts working in the IP and pharmaceutical fields. The response received on the contentious issue relating to compulsory licensing in India is presented below.

Q. Inclusion of compulsory licensing in India's National Manufacturing Policy, 2011 as a mechanism for government to effectuate technology transfer in certain sectors indicates that in India compulsory licensing provisions are being used merely as a tool to achieve government's industrial policy goals rather than towards the protection of public health in the country. Do you agree or disagree?

RESULT

Agree - 38%; Disagree - 58%; Didn't answer - 4%

Majority of the respondents refuted the argument that Indian government is using compulsory licensing provisions inappropriately to achieve its industrial policy goals rather than for protecting country's public health. The respondents therefore denied the allegation raised by the multinational companies that the compulsory licensing provisions in India are aimed primarily to extend undue benefits to the local generic drug manufacturers instead to address public health problems.

CONCLUSION AND SUGGESTIONS

Compulsory licensing is an effective mechanism to prevent the abuse of patent rights. TRIPS allows the member countries to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Through the comparative study, it was concluded that compulsory licensing provisions in India are fully TRIPS compliant. Only one compulsory license has been granted in India till date, and it was in full compliance with the existing international trade rules.

To further strengthen the compulsory licensing provisions in India, following measures are proposed:

1. A detailed guideline on compulsory licensing may be issued by the Indian Patent Office. The guideline covering various aspects of the compulsory licensing would help in removing any ambiguities in the interpretation and implementation of the compulsory licensing provisions in India.
2. An Act similar to Bayh-Dole Act in the U.S. may be enforced in India. This Act aims to encourage innovation through protection and utilisation of intellectual property generated through government funding. This Act also authorizes the government to issue compulsory licenses on the patents acquired on inventions made through the government funding in certain circumstances.
3. Provisions relating to mandatory cross-licensing between the owners of patented biotechnology inventions and registered plant variety can be implemented in India under Patents Act or Protection of Plant Varieties and Farmers' Rights Act, 2001. Such provisions aim to encourage innovation in the biotechnology sector.
4. Before making a decision of the grant of a compulsory license, the government may consider alternative mechanisms such as putting pressure on the patent holder to reduce price of the concerned product; regulating the drug prices through Drug Price Control; or direct government purchases of the patented drugs from the manufacturers at negotiated prices.
5. Indian government shall make full efforts to establish direct dialogue with the multinational

companies and involve them in government's healthcare mission as equal partners. This would encourage the companies to fulfil their corporate social responsibilities in a proactive manner and would also reduce the chances of patent abusing.

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