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 effective 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.

METHODODOLOGY

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(f)].

**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 Ciprofloxin. 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 licence 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 year 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.

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. 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.

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. 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.

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

- 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

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.

(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.

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. 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

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. 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. 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.

(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.

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.

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.

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<td>1</td>
<td>Grant of compulsory license on individual merits [Article 31(a)]</td>
<td>Section 84(6)(i-iii)</td>
<td>Yes</td>
</tr>
<tr>
<td>2</td>
<td>Prior efforts of the applicant to obtain a voluntary license is necessary [Article 31(b)]</td>
<td>Section 84(6)(iv)</td>
<td>Yes</td>
</tr>
<tr>
<td>3</td>
<td>Waiver of the prior efforts requirement [Article 31(b)]</td>
<td>Section 84(6)(iv)</td>
<td>Yes</td>
</tr>
<tr>
<td>4</td>
<td>License in the case of semi-conductor technology [Article 31(c)]</td>
<td>Section 90(1)(viii)</td>
<td>Yes</td>
</tr>
<tr>
<td>5</td>
<td>Non-exclusive basis [Article 31(d)]</td>
<td>Section 90(1)(iv)</td>
<td>Yes</td>
</tr>
<tr>
<td>6</td>
<td>Non-assignable [Article 31(e)]</td>
<td>Section 90(1)(v); 90(1)(vi)</td>
<td>Yes</td>
</tr>
<tr>
<td>7</td>
<td>Predominant use for the domestic market [Article 31(f)]</td>
<td>Section 90(1)(vii)</td>
<td>Yes</td>
</tr>
<tr>
<td>8</td>
<td>Termination of the compulsory licence [Article 31(g)]</td>
<td>Section 94</td>
<td>Yes</td>
</tr>
<tr>
<td>9</td>
<td>Adequate remuneration to the patentee [Article 31(h)]</td>
<td>Section 90(1)(i)</td>
<td>Yes</td>
</tr>
<tr>
<td>10</td>
<td>Decision on compulsory license subject to judicial review [Article 31(i)&amp;(j)]</td>
<td>Section 117A (Decision of the Controller appealable at IPAB)</td>
<td>Yes</td>
</tr>
<tr>
<td>11</td>
<td>Special considerations in the case of anti-competitive practices [Article 31(k)]</td>
<td>Sections 84(6)(iv); 90(1)(ix)</td>
<td>Yes</td>
</tr>
<tr>
<td>12</td>
<td>Licensing of related patents [Article 31(l)]</td>
<td>Section 91</td>
<td>Yes</td>
</tr>
<tr>
<td>13</td>
<td>Export of patented pharmaceutical products (Paragraph 6 decision of the Doha Declaration)</td>
<td>Section 92A</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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.

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

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Ground for compulsory license (CL)</th>
<th>Provision in the U.S. law</th>
<th>Provision in Indian Patents Act</th>
</tr>
</thead>
</table>
| 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

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Ground for compulsory license (CL)</th>
<th>Provision in the European Regulation</th>
<th>Provision in Indian Patents Act</th>
</tr>
</thead>
</table>
| 1      | Export of patented pharmaceutical products under paragraph 6 decision of the Doha Declaration | Regulation 816/2006 (EC)  
No | 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

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

<table>
<thead>
<tr>
<th></th>
<th>Predominant use for the domestic market</th>
<th>Article 53</th>
<th>Section 90(1)(vii)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>Prior efforts of the applicant to obtain a voluntary license is necessary</td>
<td>Article 54</td>
<td>Section 84(6)(iv)</td>
</tr>
<tr>
<td>9</td>
<td>Termination of the compulsory licence</td>
<td>Article 55</td>
<td>Section 94</td>
</tr>
<tr>
<td>10</td>
<td>Non-exclusive basis</td>
<td>Article 56</td>
<td>Section 90(1)(iv)</td>
</tr>
<tr>
<td>11</td>
<td>Adequate remuneration to the patentee</td>
<td>Article 57</td>
<td>Section 90(1)(i)</td>
</tr>
<tr>
<td>12</td>
<td>Decision on compulsory license subject to judicial review</td>
<td>Article 58</td>
<td>Section 117A</td>
</tr>
<tr>
<td>13</td>
<td>Detailed guidelines on CL</td>
<td>Measures for Compulsory Licensing of Patent Implementation, 2012</td>
<td>No similar guidelines</td>
</tr>
</tbody>
</table>
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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A COMPARATIVE STUDY OF PATENT OPPOSITION IN U.S., EUROPE, CHINA AND INDIA

Vipin Mathur*, Dr. B. P. Nagori** & Dr. Mahendra Tiwari***

INTRODUCTION

Patents provide valuable monopoly right to the patent owners or patentees over their inventive products or processes. A patent is a legal contract between the patentee and the government, wherein, the government provides right of protection of the invention for a limited period of time after full disclosure of the invention by the patentee. Grant of the patent is a statutory process, governed by the patent regulation of the concerned country, subject to the general conditions of patentability viz. novelty, inventive step and industrial applicability. Although, patent applications go through careful examination by the patent office before patent rights are granted to the patentees, still deficient or poor quality patents may be granted sometimes erroneously. To ensure quality of the granted patents, opposition mechanisms are provided in the patenting system.

Patent opposition can be defined as “a request presented by the opposing party (a person or entity other than the patentee) to the patent office to refuse the patent application or to revoke the granted patent”¹. However, on the one hand opposition helps in preventing the wrongful grant

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of a patent, but on the other hand it may cause undue delay in the grant of the patents. The patenting system thus should strike a balance between the interests of patent applicants and need to prevent poor quality patents in order to encourage R&D as well as to ensure an effective patent prosecution process.\(^2\)

The principal law for patent grant in India is the Patents Act, 1970. To make the patent law compliant with TRIPS (Trade Related Aspects of Intellectual Property Rights) agreement, India introduced a series of amendments in its patent law, in 1999, 2002 and 2005.

The current patent law in India provides a dual mechanism of opposing patents, both before (pre-grant) and after the grant (post-grant) of patents. However, the provisions for patent opposition in India have been under criticism both at national and international fronts.\(^3,4,5\)

Pre-grant opposition is perceived as a decided weakness of India’s new patent regime.\(^6\) It has been argued that the pre-grant opposition in India causes undue delay in the patent grant and is a burden on the patent applicants.\(^7,8\) In 2013, Dr. S. Jagathrakshakan, the then Minister of State for Commerce & Industry, in a written reply in Lok Sabha mentioned that pre-

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\(^4\) ‘2014 Special 301 Report’ Office of the United States Trade Representative (April 2014).


\(^8\) Shanker, above, n 2.
grant opposition is one of the reasons for delay in the grant of patents in India.\(^9\) As on July 31, 2015 over 2.26 lakh patent applications were pending with patent offices in India for approval.\(^10\) Organisation of Pharmaceutical Producers of India (OPPI) advocates that like other leading countries and progressive nations, India should move away from pre-grant opposition.\(^11\)

Looking at the growing concerns over this issue, the present study was aimed to propose measures to strengthen the current patent opposition system in India. For this, regulations for patent opposition in U.S., Europe, China and India were studied thoroughly. The Indian regulations were compared with the regulations in U.S., Europe and China. Important case laws were also reviewed in this context. Further, empirical data on the contentious issues in the patent opposition system in India was collected through research questionnaire.

Based on the comparative study, review of case laws and analysis of the collected empirical data, suggestions for strengthening the patent opposition system in India are proposed.

**PATENT OPPOSITION IN THE U.S.**

The U.S. patent law was amended on September 16, 2011 by the Leahy-Smith America Invents Act (AIA). The AIA made significant changes in the U.S. patent law, including switch from the previous “first-to-
invent‖ to the current “first-inventor-to-file” system and introduction of new provisions for patent opposition.

Under the current law, third parties may challenge patents at U.S. Patent and Trade Mark Office (USPTO) through the following processes:

A. Preissuance Submissions by Third Parties
B. Post-Grant Proceedings
   a. Post-grant review
   b. Inter partes review
   c. Ex parte re-examination

A. Preissuance Submissions by Third Parties

Any third party may challenge the pending patent applications by submitting relevant prior art in writing to USPTO. The prior art may be submitted after the publication of the patent application and may be in the form of any patent, published patent application, or other printed publication of potential relevance to the examination of the application. The submission must be made before the earlier of - (i) the mailing of a Notice of Allowance; or (ii) the later of - 6 months after publication date; or the date of first rejection of any claim.

The submission shall include (i) a concise description of the relevance of each submitted prior-art document, (ii) a statement by the submitter that the submission complies with the law, and (iii) the prescribed fee. The submissions can also be made electronically on the USPTO website. During the process of third party submission, a real party in interest can remain anonymous by having someone else make the third-party submission for them (straw man approach)\(^\text{12}\).

The submitted material is placed in the patent application file for consideration by the examiner. If the submission is made within the statutory time limit, the submitted prior art can become an important ground of rejecting the deficient patent claim(s). This is an *ex-parte* procedure therefore, the prior art submitter (third party) can not contest the patent grant in-person by requesting a hearing or to contact the examiner personally. However, this procedure has the advantage of avoiding undue delays in patent grant. At the same time, it also helps in enhancing examination effectiveness and efficiency by bringing the most relevant prior art to examiner’s attention at an early stage during the patent prosecution\(^\text{13}\). In contrast to post-grant review and *inter partes* review, third party pre-grant submission does not precludes the third party to rely upon the submitted prior art to contest the validity of the issued patent in future (the estoppel is not created)\(^\text{14}\).

This provision is applicable for any patent application filed before, on, or after September 16, 2012.

**B. Post-Grant Proceedings**

The U.S. patent law provides a number of administrative post-grant proceedings through which third parties can challenge the validity of the granted patents at USPTO, and request for the revocation of one or more of the granted claims. These proceedings are - post-grant review, *inter partes* review and *ex parte* re-examination.


a. Post-grant review

Post-grant review (PGR) is applicable for patents having effective filing date on or after March 16, 2013.

Any third party may file a petition with the USPTO to institute a post-grant review of a patent requesting to cancel its one or more claims as unpatentable. The post-grant review can be filed on any of the grounds of non-patentable subject matter; lack of novelty; obviousness; failure to comply with the written description; enablement or definiteness requirements of 35 USC § 112 and failure to comply with requirements with respect to reissue patents. PGR shall be filed within nine months of the grant or reissuance of the patent.\(^{15}\)

The petition shall identify all real parties in interest (petitioner cannot remain anonymous). It must identify and provide detailed arguments and evidence against the disputed claims and be accompanied with the applicable fee. The petitioner must supply copies of the petition and the evidence to the patent owner.\(^{16}\) PGR is conducted by the Patent Trial and Appeal Board (PTAB) sitting in panels of three administrative judges having both legal and technical competence.

PGR is instituted only if the USPTO determines that it is more likely than not that at least one of the claims challenged in the petition is unpatentable or if the petition raises a novel or unsettled legal question that is important to other patents or patent applications (threshold to institute PGR). The parties to PGR (patent owner and the petitioner) have the right to appear in oral hearing as part of the proceeding.


A PGR shall not be instituted, if before filing the PGR, the petitioner files a civil action in the US court challenging the validity of a claim of the patent. If the petitioner files the civil action after filing the PGR, that civil action shall be automatically stayed. However, the stay shall be lifted if the patent owner moves the court to lift the stay; or the patent owner files a civil action or counterclaim alleging that the petitioner has infringed the patent; or the petitioner moves the court to dismiss the civil action.

During a PGR, the patent owner can amend the patent either by cancelling any challenged claim or proposing a reasonable number of substitute claims. The amendment however, must not enlarge the scope of the claims of the patent or introduce any new matter.

The PTAB shall issue final decision on PGR within one year from the instituting the PGR. This time limit is extendable by maximum six additional months. Any party to the PGR may appeal the final decision to the Court of Appeals for the Federal Circuit. In the case of a settlement between the petitioner and the patent owner occurs, PGR can be terminated upon a joint request made by both the parties.

After the PTAB issues a final decision, the petitioner will be estopped from challenging the validity of the same patent on any of the ground(s) already raised by him during the PGR in any subsequent proceedings. This estoppel will not be applicable in the case of termination of PGR due to settlement between the parties.

The law also provide for a specific type of PGR for patents claiming covered business methods (methods for performing data processing and other operations used in administration of financial products or services). This provision is transitional in nature and would be valid till September 16, 2020.
b. **Inter partes review**

Once the window for post-grant review (PGR) has passed, *Inter Partes* Review (IPR) provides an additional option for the third parties to challenge validity of the granted patents. IPR is applicable for any patent issued before, on, or after September 16, 2012.

Any third party may file a petition with the USPTO to institute *Inter partes* review nine months after the grant or reissuance of the patent or after conclusion of PGR, whichever is earlier.

An IPR is instituted only if the USPTO determines that there is a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition (threshold to institute IPR). IPR can be filed only on the grounds of lack of novelty and obviousness. Remaining provisions of IPR are similar to that of the PGR.

c. **Ex parte reexamination**

Through *ex parte* reexamination, any person including a third party or the patent owner may request USPTO to re-examine one or more claim(s) of a granted patent on the basis of any prior art consisting of patents or printed publications. The request must be in writing and must be accompanied by payment of the prescribed re-examination fee.

*Ex parte* re-examination is conducted by the Central Reexamination Unit ("CRU") of USPTO. USPTO will conduct the re-examination proceedings if it determines that a “substantial new question of patentability” affecting any claim of the concerned patent exists (threshold to institute *ex parte* reexamination). After such a determination by USPTO, the patent owner is asked to file a statement on such question, including any amendment to his patent and any new claim(s) he may wish to propose. The

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requestor of the *ex parte* re-examination is then allowed to file a reply to the statement filed by the patent owner. After filing the reply, the requestor would not be allowed to participate further in the re-examination proceedings\(^{18}\). The patent owner will then be permitted to propose any amendment to his patent and/ or any new claim(s). The amendment however, must not enlarge the scope of the claim(s).

The patent owner can appeal the final decision of USPTO in the *ex parte* re-examination to the Patent Trial and Appeal Board (PTAB). No legal estoppel for the requestor is created by an *ex parte* re-examination proceeding.

**PATENT OPPOSITION IN EUROPE**

European patent refer to patents granted under the European Patent Convention (EPC). European Patent Office (EPO) grants the European patents via a single, harmonised procedure. A granted European patent becomes enforceable in any/ all of the member countries to the EPC, when the patent owner validates the patent in the concerned member country / countries by filing the prescribed fee and submitting a translation of the specification in an official language of the national patent office within the prescribed time limit.

The EPC provides for the opposition of patents through:
A. Observations by Third Parties
B. Post-Grant Opposition

**A. Observations by Third Parties**

After the publication of the European patent application, any third party may file observations at EPO concerning the patentability of the

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invention described in the patent application. However, the party shall not be allowed to take part in the proceedings. The observation can be filed on the grounds of lack of novelty and/or inventive step, clarity, sufficiency of disclosure, patentability and unallowable amendments.

The observations must be filed in writing in English, French or German and shall include (i) a statement of the grounds on which they are based and (ii) the documentary evidence and publications in support of the arguments. The evidence may be filed in any language, however, the EPO may request to file its translation into one of its official languages, and otherwise the evidence will be disregarded. Filing observations at EPO is free of charge and it can be made electronically on the EPO website. The third parties may remain anonymous, if they so wish while filing the observations.\textsuperscript{19}

The filed observations are communicated promptly to the patent applicant and the applicant is allowed to comment on it. If the examiner finds that the observations raise any question on the patentability of the invention, they are taken into account during the remaining prosecution of the patent application. Observations received after the conclusion of prosecution will not be taken into account and will simply be added to the non-public part of the file. There is no rule of estoppel creation during filings the observations by third parties at EPO.

B. Post-Grant Opposition

Within nine months of the grant of a European patent, any person may file notice of opposition of the patent at EPO. The opposition applies to the European patent in all the contracting states in which that patent has been enforced. The patent owner and the opponents shall be the parties to the opposition proceedings and can take part in the oral hearings.

\textsuperscript{19} Guidelines for Examination in the EPO, Part E, Chapter V-3 (November 2015).
Opposition may be filed on the grounds of – lack of patentability under Articles 52 to 57 of EPC, insufficient disclosure and incorporation of subject matter beyond the scope of the application as filed. The notice of opposition shall be filed in writing and should identify the patent opposed. The notice shall include the particulars of the person filing the opposition, a statement of the extent to which the patent is opposed and of the grounds on which the opposition is based, evidence that supports the grounds for opposition and the prescribed fee²⁰.

The actual opponent can remain anonymous, if he so wishes by filing the opposition through his/ her representative.

The Opposition Division of the EPO is responsible for the examination of oppositions against any European patent. It consists of three technically qualified examiners, at least two of whom shall not have taken part in the proceedings for grant of the patent to which the opposition relates. One of these two examiners shall be the chairman of the Opposition Division. Opposition Division gives the patent owner an opportunity to file observation and/or amend the patent. The amendment however, must not enlarge the scope of the claims of the patent or introduce any new matter²¹.

Unlike in U.S., in Europe there is no automatic stay in national courts if a civil action for the revocation of the patent is filed in parallel with the post-grant opposition. National courts have discretion to either stay the national proceedings until the ongoing opposition proceeding is completed or allow the revocation proceedings to continue.


There is no rule of estoppel creation during post-grant opposition at EPO, which precludes an opponent to challenge the same patent at the national level on the same grounds raised at the EPO. During the opposition, if the parties reach a settlement, EPO may still continue the opposition proceedings despite the settlement.

There is no fixed time limit set for the announcement of final decision in the opposition proceedings at EPO. An opposition generally may last about two years. Any party to the post grant opposition may appeal the final decision of the Opposition Division to the EPO Board of Appeal.

PATENT OPPOSITION IN CHINA


Patents in China can be challenged through:
A. Observations by Third Parties
B. Post-Grant Invalidation

A. Observations by Third Parties

According to the implementing regulations of the Chinese patent law, after publication of a patent application any person can submit observations at SIPO regarding non-conformity of the application with the provisions of the Patent Law\(^\text{22}\). These third party submissions are referred to as “public observations”. The Observations can be submitted until the date of announcing the grant of the patent. Public observations are admissible for invention patents only and not for utility model patents.

Observations can be submitted on any ground of rejecting a patent application by SIPO, including lack of novelty, creativity or practical use; insufficiency of disclosure; ineligible subject matter; double patenting, etc.

Third parties can submit their arguments and the documentary evidence (if any) along with the official form prescribed by SIPO for submitting the observations, either electronically or in paper form. There is no official fee for filing the observations. The third party can also file the observations anonymously\textsuperscript{23}. There is no rule of estoppel creation during filings the observations by third parties at SIPO.

B. Post-Grant Invalidation

Prior to 1992, the Chinese patent law provided for a pre-grant opposition procedure. However, due to delays in the grant of patents, the pre-grant opposition was abolished in 1992, and a new post-grant opposition procedure was introduced. From 1992 to 2000, SIPO had a post-grant opposition procedure and a post-grant invalidation procedure. The differences between the two procedures included time allowed for filing a petition, the grounds on which the claim(s) can be invalidated and the forum for resolving the petition. However, the two overlapping proceedings, specifically post-grant opposition, increased the burden of examination on the SIPO and therefore, in 2001 the patent opposition system was completely abolished in China.

Currently, the only way to challenge a granted patent in China is through the post-grant invalidation procedure. Any individual or entity may submit request to the Patent Re-examination Board (PRB) to declare a patent invalid on the ground that such patent does not conform to the

conditions for granting patent rights under the law\textsuperscript{24}. Requests for invalidation can be filed in writing at any time after the grant of a patent.

The request for patent invalidation includes a written statement about the grounds of invalidity, supporting evidence and the prescribed fee. The requestor may file supplemental grounds and evidence within one month from the date of filing of the request. There are a large number of grounds available for patent invalidation including - lack of novelty, creativity or practical use; insufficiency of disclosure; inadequate enablement; unpatentable subject matter; addition of new matter after patent filing; double patenting; claims are not supported by the description; claims lacking clarity or being indefinite\textsuperscript{25}.

A panel consisting of 3-5 examiners is designated for the invalidation case. If the panel is satisfied that the request for invalidation complies with all formality requirements, it will forward a copy of the request and all relevant documents to the patent owner. The patent owner is then allowed to file his written response along with the supporting evidence in the prescribed time limit. Upon request by any of the parties, an oral hearing may be held. Oral hearings are similar to court sessions, including questioning of evidence, identifying facts, and debate by the two parties. At the end of the oral hearing, the panel may ask one or both parties to submit supplemental written comments\textsuperscript{26}. The patent owner may amend the patent claim(s). The amendment however, must not enlarge the scope of the claims of the patent or introduce any new matter.


PRB issues its final decision on the proceedings, in which the patent may be maintained as such, maintained as amended, completely invalidated or partially invalidated. The party who is dissatisfied with the decision of PRB may appeal the decision in the Intermediate People's Court, within three months from the date of receipt of the notification of the decision.

Rule of estoppel is applicable in which, when a decision on invalidation of the patent right is made, PRB shall not accept another request for invalidation of those patent right based on the same grounds and evidence.

In China, patent litigation proceedings are bifurcated in which patent validity and infringement issues are dealt by separate bodies (validity by PRB and infringement by the People’s Courts). Due to this bifurcated system, no parallel revocation proceeding of the patent is allowed in the People’s Courts. However, a parallel patent infringement proceeding is possible at the People’s Courts, which is typically not stayed pending the outcome of invalidation action at the PBR27.

The person requesting invalidation may withdraw his request before the PRB announces a decision on it. In such a case, the invalidation proceeding is terminated. The invalidation proceeding usually takes about two years to complete.

PATENT OPPOSITION IN INDIA
The options available for patent opposition in India are:
A. Pre-Grant Opposition
B. Post-Grant Opposition

A. Pre-Grant Opposition

U.S., Europe, China and many other countries of the world provide an *ex-parte* pre-grant procedure to the third parties for submitting relevant prior art to challenge grant of a patent. However, unlike in other countries, in India pre-grant opposition u/s 25(1) is an *inter-partes* procedure in which the third party is allowed to appear for hearings and participate in the opposition proceedings.

Any person may file a representation for opposition before the controller of patents at the appropriate patent office (Kolkata, Delhi, Mumbai or Chennai) against the grant of a patent. The representation can be filed any time after the publication of the patent application but before the grant of the patent. Further, the law mandates that no patent shall be granted before the expiry of a period of six months from the date of publication of the application, therefore third parties get at least six months after the publication of a patent application to file the representation.

The representation can be filed on any of the following grounds – wrongful obtaining of invention; anticipation by prior publication; anticipation by prior claiming in India; invention publicly known or publicly used in India; lack of inventive step or obviousness; not patentable subject matter; insufficiency of disclosure; suppression of information about foreign filing required by section 8; in the case of convention application, the application was not made within 12 months from the date of the first application made in a convention country; non-disclosure/ wrong mention of the source of biological material; and anticipation having regard to traditional knowledge of any community in India or anywhere in the world."}28.

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The representation shall include a statement of the case, evidence (if any) in support of the representation and a request for hearing, if so desired. The representation should be filed along with the prescribed form [Form 7(A)]. There is no fee applicable for filing the representation. Such representation shall only be considered when a request for examination of the application has been filed. When representation is considered, the controller gives a notice to the applicant of such consideration, along with a copy of the representation. After receiving the notice, the applicant may file his statement and evidence (if any) in support of his application. The parties are then allowed to appear for hearings. After considering the representation and submission made during the hearing, the controller may ask the patent applicant to amend the complete specification. Finally, the controller either refuses the patent application or grants the patent (as such or in the amended form).

The Indian Patent Act does not provide any specific provision for appeals against controller’s decisions in pre-grant opposition. This matter was clarified in two court cases viz. *J. Mitra & Co. Pvt. Ltd. v Asst. Controller of Patents & Designs* in the Supreme Court of India [2008] and *UCB Farchim SA v Cipla Ltd. & Others* in Delhi High Court [2010]. According to these case laws, in the pre-grant proceedings if the patent application is refused by the controller, the patent applicant may file an appeal to the Intellectual Property Appellate Board (IPAB) against the refusal. However, if the pre-grant opposition is rejected and patent is granted, the opposing person can file a writ petition in the High Court against the controller’s decision, or file a post-grant opposition u/s 25(2) (as long as that person happens to be a person interested)29.

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Rule of estoppel is not applicable in India at the pre-grant stage, and therefore same person can challenge a patent through both pre-grant and post-grant oppositions even on the same ground(s).

B. Post-Grant Opposition

Any “person interested” can file a notice of opposition u/s 25(2) to the controller of patents against a patent within one year from the grant of the patent. A “person interested” may be a person engaged in, or in promoting, research in the same field as that to which the invention described in the patent relates or an organization that has a manufacturing or trading interest in the goods connected with the patented article or which possesses patent(s) relating to the same subject. The grounds for filing a post-grant opposition are identical to the grounds of filing pre-grant opposition u/s 25(1)\(^\text{30}\).

On receipt of notice of opposition the controller constitutes an opposition board consisting of three members and nominates one of the members as the chairman of the board. The examiner, who has taken part in the proceeding for grant of patent to which the opposition relates, is not eligible to be a member of the opposition board.

The notice of opposition shall include a written statement setting out the nature of the opponent's interest, the facts upon which the case is based, relief which the opponent seeks, evidence (if any), prescribed form (Form 7) and the fee. The opponent shall forward a copy of the notice to the patent owner. The patent owner is then allowed to file his reply statement along with the supporting evidence in the prescribed time limit. The patent owner shall forward a copy of the reply statement and supporting evidence to the opponent. The patent owner and the opponent are given opportunity to

appear in the hearings. After the hearings and taking into consideration the recommendation of the opposition board, the controller shall order either to maintain or to amend or to revoke the patent. Such order of the controller is appealable by the aggrieved party (patent owner or opponent) at the Intellectual Property Appellate Board (IPAB).

In India a granted patent can be revoked before three different forums viz. the patent office through a post-grant opposition u/s 25(2) ; the IPAB through a revocation petition u/s 64; and the High Court through a counterclaim in an infringement suit u/s 64. However, the patent law does not provide any specific provision for the admissibility/ non-admissibility of parallel multiple revocation proceedings against the same patent. This issue was clarified by the Supreme Court in the case of Dr. Aloys Wobben v Yogesh Mehra and others [2014]. As per the Supreme Court decision, multiple patent revocation proceedings shall not be allowed simultaneously. Out of the three revocation proceedings available, a person interested shall be allowed to pursue only one revocation proceeding at a time, which he initiates first\(^\text{31}\). It creates provision of estoppel at the post-grant stage in the patent prosecution.

There is no provision expressly provided in the Indian patent law relating to the settlement between the parties during the opposition proceedings. The opposing party may however, withdraw his opposition before the controller makes a decision on it. In such a case, the opposition proceeding is terminated.

C. Statistics on Patent Opposition in India

Table 1 and 2 provide recent statistics on pre- and post-grant oppositions in India. The information presented in the tables has been taken from the

annual reports published by the Indian patent office and the controller’s decision published on the Indian patent office website.

Table 1: Statistics on pre-grant opposition in India

<table>
<thead>
<tr>
<th>Year</th>
<th>Total oppositions filed</th>
<th>Controller’s decisions (Including of previous years)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Total decisions</td>
</tr>
<tr>
<td>2012-13</td>
<td>262</td>
<td>11</td>
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<tr>
<td>2013-14</td>
<td>309</td>
<td>22</td>
</tr>
<tr>
<td>2014-15</td>
<td>Not available</td>
<td>30</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>63</td>
</tr>
</tbody>
</table>

Table 2: Statistics on post-grant opposition in India

<table>
<thead>
<tr>
<th>Year</th>
<th>Total oppositions filed</th>
<th>Controller’s decisions (Including of previous years)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Total decisions</td>
</tr>
<tr>
<td>2012-13</td>
<td>14</td>
<td>02</td>
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<tr>
<td>2013-14</td>
<td>08</td>
<td>05</td>
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<tr>
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<td>08</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>15</td>
</tr>
</tbody>
</table>

Data provided in the above tables indicates that as compared to other fields of technology, pharmaceutical field is most affected by the opposition proceedings in India. In the last three years, majority of the controller’s decisions are on the opposition of patents relating to pharmaceutical
inventions (44 out of the total 63 decisions in pre-grant opposition and 09 out of the total 15 decisions in post-grant opposition)

**COMPARISON OF PATENT OPPOSITION IN U.S., EUROPE, CHINA AND INDIA**

Salient provisions relating to patent opposition in U.S., Europe, China and India are compared and suggestions for India are proposed in the table 3.

**Table 3: Comparison of patent opposition in U.S., Europe, China and India**

<table>
<thead>
<tr>
<th></th>
<th>U.S</th>
<th>Europe</th>
<th>China</th>
<th>India</th>
<th>Suggestions for India</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-grant opposition</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proceeding</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ex-parte</td>
<td>Ex-parte</td>
<td>Ex-parte</td>
<td>Inter-</td>
<td>Inter-</td>
<td></td>
</tr>
<tr>
<td>preissuance</td>
<td>observatio</td>
<td>observatio</td>
<td>partes</td>
<td>partes</td>
<td></td>
</tr>
<tr>
<td>submissions</td>
<td>ns by third</td>
<td>ns by third</td>
<td>pre-grant</td>
<td>pre-grant</td>
<td></td>
</tr>
<tr>
<td>by third</td>
<td>parties</td>
<td>parties</td>
<td>opposition</td>
<td>opposition</td>
<td></td>
</tr>
<tr>
<td>parties</td>
<td>(EPC Art.</td>
<td>(Rule 48)</td>
<td>(Section</td>
<td>(Section</td>
<td></td>
</tr>
<tr>
<td></td>
<td>115)</td>
<td></td>
<td>25(1))</td>
<td>25(1))</td>
<td></td>
</tr>
<tr>
<td>Fee</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Fee be prescribed for filing inter-partes pre-grant opposition</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th></th>
<th>U.S</th>
<th>Europe</th>
<th>China</th>
<th>India</th>
<th>Suggestions for India</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estoppel Provision</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Estoppel provision be applicable while filing <em>inter-partes</em> pre-grant opposition</td>
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<tr>
<td>Threshold to institute the proceeding</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>No threshold prescribed</td>
<td>Threshold be fixed to institute an <em>inter-partes</em> pre-grant opposition</td>
</tr>
<tr>
<td><strong>Post-grant opposition</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proceeding - 1</td>
<td><em>Inter partes</em> post-grant review <em>(35 USC 321-329)</em></td>
<td><em>Inter partes</em> post-grant opposition <em>(EPC Art. 99-112a)</em></td>
<td><em>Inter partes</em> post-grant invalidation <em>(Art. 45-47)</em></td>
<td><em>Inter partes</em> post-grant opposition <em>[Section 25(2)]</em></td>
<td>---</td>
</tr>
<tr>
<td>Threshold to institute the proceeding</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Threshold be fixed to institute a post-grant opposition</td>
</tr>
<tr>
<td>Estoppel Provision</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes (as per the Supreme Court decision)</td>
<td>The provision be incorporated in the Patents Act, 1970</td>
</tr>
<tr>
<td>Proceeding</td>
<td><em>Inter partes</em></td>
<td>No similar</td>
<td>No similar</td>
<td>No similar</td>
<td>---</td>
</tr>
</tbody>
</table>
COLLECTION & ANALYSIS OF THE EMPIRICAL DATA

A questionnaire was formulated that mentions 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 related to IP field. The response received on the question based on the contentious issues in the patent opposition system in India is presented below.

Q. Current patent opposition procedure in India causes undue delay in the patent grant and is a burden on the applicants because same person may, at minimal cost can challenge a patent on the same grounds through both pre-grant and post-grant oppositions. To avoid such undue delays in patent grant, the pre-grant challenge should be limited to third party submission of relevant printed prior art to the patent examiner, allowing oral hearings of the interested third parties at the post-grant opposition stage only. Do you agree or disagree?

Result: Agree - 70.77%; Disagree - 29.23%

Majority of the respondents (70.77%) agreed that the provision of pre-grant opposition in India leads to undue delay in the patent grant. And therefore, at the pre-grant stage, current inter-partes pre-grant procedure should be replaced with the provision of ex-parte third party prior art submission.
CONCLUSION AND SUGGESTIONS

Opposition system is an important tool for controlling poor quality patents. However, since patents have a limited term, a weak patent opposition system may lead to undue loss to the innovators due to delays in the patent grant. Concerns have been raised over the efficiency of patent opposition system in India. This article examined and compared the provisions relating to patent opposition in U.S., Europe, China and India. On this issue empirical data was also collected. Following measures are proposed for strengthening the patent opposition system in India –

(1) Adoption of *ex-parte* prior art submission system: U.S., Europe and China follow *ex-parte* prior art submission process at the pre-grant stage. However, India is among a limited number of countries which still permit *inter-partes* pre-grant opposition. In order to avoid undue delays in patent grant, India should abolish the *inter-partes* pre-grant opposition and adopt the *ex-parte* prior art submission process. The *ex-parte* prior art submission is advantageous as it permits speedy prosecution of the patent applications, yet allowing third parties to bring the most relevant prior art to examiner’s attention at an early stage of the prosecution.

(2) Fee for filing pre-grant opposition: Presently, Indian patent office does not charge any fee from the person filing a pre-grant opposition. Since, in India the current pre-grant opposition is an *inter-partes* procedure involving hearings of the parties, an appropriate fee should be charged from the person filing pre-grant opposition for utilizing services of the patent office. Charging of fee will also put a check on the filing of frivolous or misleading oppositions.

(3) Estoppel provision: Estoppel prevents the opponent from challenging validity of the same patent in any subsequent opposition proceedings on the ground(s) already raised by him in the previous proceeding. In
India the same person is allowed to challenge a patent through both pre-grant and post-grant oppositions even on the same ground(s). This may lead to undue lengthening of the patent grant. Further, a particular patent can be targeted purposefully by the competitors, causing substantial loss of effective patent term to the patent owner. To avoid this, estoppel provision should be incorporated in the Indian patent law at the pre-grant stage. At the post-grant stage the Supreme Court has already clarified that estoppel shall be created that would allow an interested person to pursue only the first initiated revocation proceeding. This provision of estoppel should now be explicitly incorporated in the Patents Act, 1970.

(4) Threshold requirement: Threshold to institute the opposition proceeding puts a check on filing of frivolous or misleading oppositions. Threshold requirement to institute post-grant opposition is included in the U.S. patent law. Indian patent law should also adopt the threshold requirement and fix threshold to institute both pre- and post-grant oppositions.
Research Questionnaire

This survey is being conducted as part of the PhD research work on "Patenting of Pharmaceuticals: A Comparative Study of the Laws in U.S., Europe, China and India". The research aims to suggest measures to strengthen the current regulations for patenting of pharmaceuticals in India.

In this context, we have formulated this questionnaire that mentions the questions/ concerns raised over the current patenting system in India at national and international fronts in the recent time.

We request you to kindly spare your precious time and provide your expert opinion by answering the questions mentioned below and/or writing your views/comments in the space provided.

We assure you that the information provided by you will be used only in aggregate, wholly and solely for the purpose of research and will be kept strictly confidential.

Ph.D. Scholar
Vipin Mathur
Jagannath University, Jaipur, Rajasthan, India

Supervisor
Prof. Dr. B. P. Nagori
Director, Pharmacy Wing
Lachoo Memorial College of Science & Technology (Autonomous)
Jodhpur, Rajasthan, India

Joint Supervisor
Prof. Dr. Mahendra Tiwari
Dean & HoD, Dept. of Law,
Jagannath University, Jaipur, Rajasthan, India

Please provide your details below:

Name : _____________________________
Designation : _____________________________
Organization : _____________________________
Country : _____________________________
Contact Number : _____________________________
E-mail : _____________________________

1. The main responsible factor for India’s consistently poor annual FDI (Foreign Direct Investment) inflows is its weak national IP environment as compared to the other BRIC (Brazil, Russia and China) and middle-income countries.

□ Agree □ Disagree

Any other comments ____________________________________________
2. 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.

☐ Agree       ☐ Disagree

Any other comments ____________________________________________

3. Article 27 of TRIPS enlists the subject matter that can be excluded from the patent coverage. Section 3 (d) of the Indian Patents Act, which excludes from patentability any new forms of known substances lacking enhanced efficacy, is inconsistent with the TRIPS Agreement because subject matter of section 3(d) is not included in the permissible list of exclusions for patentability mentioned in the Article 27. Furthermore, section 3 (d) also conflicts with the non-discrimination principle provided by the Article, as this section sets a higher threshold of patentability specifically for the pharmaceutical inventions.

☐ Agree       ☐ Disagree

Any other comments ____________________________________________

4. India’s current IP policy is inducing barrier to trade and is an obstacle in the business environment in India for the companies of foreign countries such as U.S. and Europe.

☐ Agree       ☐ Disagree

Any other comments ____________________________________________

5. India should implement patent term restoration provision as available in a number of countries such as US, Europe and Australia, which aims at restoring a portion of the patent term granted to innovative pharmaceutical products that is lost, due to the prolonged research, development, and regulatory approval periods of such products.

☐ Agree       ☐ Disagree

Any other comments ____________________________________________

6. Current patent opposition procedure in India causes undue delay in the patent grant and is a burden on the applicants because same person may, at minimal cost can challenge a patent on the same grounds through both pre-grant and post-grant oppositions. To avoid such undue delays in patent grant, the pre-grant challenge should be limited to third party submission of relevant printed prior art to the patent examiner, allowing oral hearings of the interested third parties at the post-grant opposition stage only.

☐ Agree       ☐ Disagree

Any other comments ____________________________________________
7. India has a large number of inventions that may not satisfy the criteria of patentability but are novel, utilitarian and inventive in their own spheres. Such petty patents or “utility models” has been successfully applied in many countries but is not available in India. This leaves out a large number of inventors particularly the MSMEs from protecting their inventions. India should therefore, introduce provisions for patenting of utility models.

□ Agree □ Disagree

Any other comments __________________________

8. India should sign and become member of the Patent Law Treaty [administered by the World Intellectual Property Organization (WIPO)], that aims to harmonize and streamline formal procedures in respect of national and regional patent applications and patents.

□ Agree □ Disagree

Any other comments __________________________

9. Currently, more than 75% of the patent applications filed in India belong to foreign citizens. In your opinion, the prime reason behind the low rate of patent filing by Indian citizens in India is:

□ Lack of awareness about IPR and patents in India

□ Lack of R&D and innovation by Indians

□ High cost of patent filing in India

Any other reason/ comments __________________________

10. Do you agree that courts in India are overburdened, leading to long delays in case processing, therefore there is an urgent need to strengthen IPR enforcement mechanism in the country by increasing judicial efficiency and reducing court backlogs through measures such as - electronic case management, fast-track procedures, IP specialized judges and separate patent benches in the High Courts?

□ Agree □ Disagree

Any other comments __________________________

11. Do you agree that there is a need to improve working efficiency of the Indian Patent Offices, and therefore measures such as - hiring more patent examiners, training of the officials, and complete digitalization of the patent databases and procedures at the patent offices are utmost necessary?

□ Yes □ No

Any other comments __________________________
12. Do you agree that the current provisions for “working of patents” and its formal reporting in India are vague and require clarity on the aspects such as - whether importation of the patented products amounts to local working of a patented invention; use of words like partly, adequately and fullest extent in the Form 27; and disclosure and publication of sensitive and confidential business information like quantum and value of the patented product worked in the country?

☐ Yes ☐ No

Any other comments ________________________________

13. Do you agree that the section 8 requirement of the India Patents Act relating to information and undertaking regarding foreign applications is unnecessarily burdensome and targets the foreign patent applicants in a discriminatory manner? Further, the penalty for failure to comply with this section is extreme in India as compared to that of the other countries with similar but less onerous administrative requirements?

☐ Yes ☐ No

Any other comments ________________________________

14. Do you agree that India should adopt the patent linkage system that provides a transparent pathway for adjudication of patent validity and infringing issues before the marketing of a generic drug or biosimilar product?

☐ Yes ☐ No

Any other comments ________________________________
FORM 27
THE PATENTS ACT, 1970
(39 of 1970)
&
The Patents Rules, 2003

Statement regarding the working of the patented invention on commercial scale in India
[See section 146(2) and rule 131(1)]

1. Insert name, address and nationality.
In the matter of Patent No. .................. of ...............

(We) .................................................................

.................................................................

2. State the year to which the statement relates
The patentee(s) or licensee(s) under Patent No. .......... hereby furnish the following statement regarding the working of the patented invention referred to above on a commercial scale in India for the year ..........

3. Give whatever details are available.

   (i) The patented invention:
   
      (a) if not worked: reasons for not working and steps being taken for working of the invention.
      (b) If worked: quantum and value (in Rupees), of the patented product:
          i) manufactured in India
          ii) imported from other countries. (Give country wise details)

   (ii) the licensees and sub-licensees granted during the year;
   (iii) state whether public requirement has been met partly/adequately/to the fullest extent at reasonable price

The facts and matters stated above are true to the best of my/our knowledge, information and belief.

Dated this ...................... day of .................. 200 ...........

4. To be signed by person(s) giving the statement.

Signature ...........................

To
The Controller of Patents
The Patent Office
at .........................

Note: (a) Strike out whichever is not applicable.
FORM 27

THE PATENTS ACT, 1970
(39 of 1970)

and

The Patents Rules, 2003

Statement regarding the working of the patented invention on commercial scale in India

[see section 146 (2) and sub-rule (1) of rule 131]

<table>
<thead>
<tr>
<th>1. Insert name, address and nationality of the patentee(s) or licensee(s).</th>
<th>In the matter of patent No. ..................granted on DD/MM/YYYY</th>
</tr>
</thead>
<tbody>
<tr>
<td>I/We ...........................................................................................................hereby furnish the following statement about the working of said patent on commercial scale:</td>
<td></td>
</tr>
<tr>
<td>2. State the calendar year to which the statement relates.</td>
<td>For the year..............................</td>
</tr>
<tr>
<td>3. The details of working.</td>
<td>By Patentee:</td>
</tr>
<tr>
<td></td>
<td>Item</td>
</tr>
<tr>
<td></td>
<td>a) Manufactured in India</td>
</tr>
<tr>
<td></td>
<td>b) Imported from other countries (give country wise details)</td>
</tr>
<tr>
<td></td>
<td>c) Grant of Licenses</td>
</tr>
<tr>
<td>By licensee:</td>
<td>Exclusive □ Non-exclusive □</td>
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<tr>
<td></td>
<td>Item</td>
</tr>
<tr>
<td></td>
<td>a) Manufactured in India</td>
</tr>
<tr>
<td></td>
<td>b) Imported from other countries (give country wise details)</td>
</tr>
<tr>
<td></td>
<td>c) Grant of sub-licenses</td>
</tr>
</tbody>
</table>
4. Details of products commercialized by utilizing the patent

5. If not worked, please state the reason for not working and steps being taken for working.

By Patentee(s)/Licensee(s):

6. To be signed by person(s) giving the statement.

Signature of Patentee/Licensee

7. Name of the natural person who has signed along with designation and official seal, if any.

(.............................)

To,

The Controller of Patents
The Patent office
at ..........................

Note:- (i) Strike out whichever is not applicable.

(ii) Repeat boxes in case of more than one entry."