INTRODUCTION

1.1 Background

Intellectual Property Laws govern the grant, enforcement and other matters related with Intellectual Property Rights (IPRs) including patents, trade secrets, industrial designs, trademarks, geographical indications, plant varieties, copyright etc. IPRs are intangible assets, and in the current knowledge-driven economy they are considered more important than the tangible assets (e.g. land, building, raw material etc.) for the success of a business\(^1\). Considering the increasing importance of intellectual property rights in the industrial growth of the nation, this field is of significant importance. IPRs are regarded as a source of national wealth.

Patent is one of the major forms of intellectual property rights used in the industries. Patent is an exclusive right which prohibits unauthorized use of a new, inventive and useful product/process by the third parties. It provides a monopoly to the patent owner over the making, using, selling and importing of the patented invention in the country for a limited term of 20 years. Patenting system plays a significant role in innovation and technology driven industries such as Pharmaceutical industry. Cost of developing the new pharmaceutical products is extensively high; therefore to recover this high cost it is imperative for the pharmaceutical companies to protect their new products from any unauthorized commercial use in the market through patent protection.

The main benefits of patenting system are\(^2,3\)

(i) **Encouragement to R & D**: Patents disseminate the latest knowledge across the globe. They encourage the scientific community to develop technologically better, economic and more efficient products/processes.

(ii) **Reward to innovators**: Patent is an exclusive rights, thus it prevents the unauthorized commercial use of the patented product/process by the
competitors. It rewards the inventor for his intellectual efforts to create new, inventive and useful products/processes.

(iii) **Compensation**: It compensates the inventor for his investment in the form of time, money and resources to carry out the inventive work.

(iv) **New and better quality products**: Patents encourage the development of new and better quality products, thus it is beneficial for the public.

(v) **Economic development**: Patenting system creates the environment of healthy competition in the market that leads to overall economic development in the country.

(vi) Limited term of patents encourage quick commercialization of the invention.

(vii) Patents avoid duplication of the research work.

(viii) Patents are the storehouses of technical information, thus they increase the general pool of technical information available to the public and researchers.

(ix) Patents facilitate transfer of technology.

(x) Full disclosure of the invention enables others to use the invention after the expiry of the patent term.

Patent law lays down the legislation pertaining to acquisition, enforcement, transfer and other matters related to the patent rights. In India the governing law for patent protection is the Patents Act, 1970. This Act has been amended in the years 1999, 2002 and 2005 to make it compliant to the provisions of TRIPS agreement.

1.1.1 **Patent filing in India**

An overall growth in patent filing has been observed during the last few years in India. The trend in patent filing in India over the last five years is shown in Figure 1.
However, proportion of patent filing by the Indian citizens in the total patent filed in India is quite low. Only one in every six patents granted in India over the last 10 years belongs to the Indian inventors. Break-up of patents granted in India during 2006-15 is shown in Figure 2.
According to the World Intellectual Property Organisation (WIPO)\textsuperscript{4}, out of the total 214,500 PCT applications filed in 2014, Indian applicants contributed for only 1,394 applications, as compared to 61,492; 58,737; and 25,539 PCT applications filed by the applicants from U.S., Europe and China respectively (Figure 3).

As per the data presented above it is evident that patent filing by the Indian applicants at both national and international levels is quite low. Therefore, measures are required to be taken to encourage patent filing by the Indian citizens.

According to one report, it takes on an average six years for a patent application to get approved in India. In contrast, the average approval time for patent applications in the U.S. and U.K. is three years\textsuperscript{7}.

\textbf{1.1.2 Pharmaceutical industry in India}

Indian Pharmaceutical Industry is one of the most vibrant sectors of the Indian Industry. There are more than 20,000 registered pharmaceutical manufacturing
units (including 5 Central Public Sector Units) in India. The Pharmaceutical industry in India meets around 70% of the country's demand for bulk drugs, drug intermediates and pharmaceutical formulations.

Indian Pharmaceutical Industry has expanded drastically in the last two decades. India is the largest provider of generic drugs globally. Indian pharmaceutical industry is the 3\textsuperscript{rd} largest in the world by volume and 13\textsuperscript{th} in value\textsuperscript{8}. Indian generics account for 20% (in terms of volume) of the total global exports of generics\textsuperscript{9}. Indian drugs are exported to around 200 countries in the world including countries with highly regulated markets such as USA and Europe.

Current market size of Indian pharmaceutical industry is US$ 20 billion and it is expected to grow to US$ 55 billion by 2020\textsuperscript{10}. Despite of a predicted increase in the total export value of pharmaceuticals from the country, the growth rate of pharmaceutical export from India is expected to be slowed down significantly by 2020. According to a joint report by TechSci Research and the Associated Chambers of Commerce of India (ASSOCHAM), the Compound Annual Growth Rate (CAGR) of pharmaceutical export from India will be slowed down to only 7.98\% by 2020 against the current CAGR of 14.77\%\textsuperscript{11}. Factors responsible for the slowdown in growth rate of pharmaceutical export include, tightening of drug regulations in the major importing markets such as U.S., Russia and Africa; a steep decline in the value of currency in the emerging markets, and an increase in pricing pressures for generic companies in the international market. Further, it is anticipated that in the next decade there would a decline in the launch of new drugs by the innovator companies, which would further lessen the opportunities for generic drug companies. To face the challenge of expected slowdown in the generic drug market, it is imperative for the Indian pharmaceutical companies to diversify their product range and focus on R&D and innovation\textsuperscript{12}. 

---

Page 5 of 184
1.2 Historical perspective and conceptual framework

1.2.1 Brief history of Indian patents law\textsuperscript{13,14}

The patent system in India first emerged when India was under the British rule. The first Patents Act in India, the Act VI of 1856 was based on the British Patent Law, 1852. The Act was soon repealed by the Act IX of 1857 since the former was introduced without the approval of the Queen. In 1859, the Act of granting exclusive privileges to inventors, the Act XV of 1859 was passed. The main objective of this Act was to provide the English patent holders a controlling position in the Indian market. The 1859 Act was further amended in 1872 by the addition of the provisions of the Patents and Designs Protection Act. However, after few years all the existing provisions for patents were repealed by the Act V of 1888. Subsequently, the India Patents and Designs Act, 1911 again replaced all the existing provisions on patents. The 1911 Act was amended in 1920, 1930 and 1945.

After independence, it was felt that there was a need to revise the patent legislation in order to make it compliant with the existing political and economical conditions of the country. In order to implement a comprehensive patent law in the country the Government of India constituted a committee under the Chairmanship of Justice Bakshi Tek Chand. The committee reviewed the patent law in India and submitted its interim report in 1949. The committee recommended that food and medicine should be made available to public at cheapest price, and at the same time reasonable compensation shall be given to the patentee. Following the recommendations of the committee, the India Patents and Designs Act, 1911 was amended in 1950 by the Act XXXII of 1950. In 1957, the Government of India appointed another committee under the chairmanship of Justice N. Rajagopala Ayyangar to re-examine and review the patent law in India and recommend the government accordingly. The committee submitted its report in 1959. On the basis of the report, the Patents Bill in 1965 and thereafter an amended bill in 1967 was
introduced in the parliament. Consequently, the Patents Act was passed in 1970 and the Patents Rules were published in 1972.

The Patents Act, 1970 reflected the concerns of developing countries in the area of patenting. It is considered as an exemplary piece of patent legislation that was aimed to balance the interests of both the common man and the inventors. According to the provisions of this Act no product patent but only process patents could be granted for inventions relating to food, drugs and chemicals.

In 1995, India signed the TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement. To make the Indian patent law compliant with TRIPS, the Patents Act, 1970 was amended three times, by the Patents (Amendment) Act, 1999; the Patents (Amendment) Act, 2002; and the Patents (Amendment) Act, 2005. Through these amendments significant changes were introduced in the Indian Patents Act, which include introduction of product patent regime; 20 years uniform term of patent for all categories of inventions; definition of the term “invention” made consistent with TRIPS agreement; mere discovery of new form, new property or new use of a known substance made patentable only under certain exceptional conditions (provision to prevent patent evergreening); introduction of modified provisions related to pre-grant and post-grant oppositions; and introduction of provisions for the grant of compulsory license for the export of patented pharmaceutical products under certain conditions.

The Patents Rules, 1972 were replaced by the Patents Rules, 2003. The new rules were further amended by the Patents (Amendment) Rules 2005, the Patents (Amendment) Rules 2006, the Patents (Amendment) Rules 2012 and the Patents (Amendment) Rules 2014. Recently, the Draft Patents (Amendment) Rules, 2015 were published on October 26, 2015. The draft
rules aim to introduce various changes in the patent regulations including - introduction of expedited patent examination; PCT application can be filed in India in the amended form; compulsory e-filing for the patent agents; time for FER reply to be reduced to 4 months from the existing 12 months; hearing can be held through video conferencing etc.¹⁵.

1.2.2 International treaties
Country’s patent environment gets affected in a significant way by various treaties/ conventions on IPR/ patents taking place at the international level. Salient features of main international treaties/ conventions took place in the field of patents are described below.

1.2.2.1 Paris Convention
Paris Convention for the Protection of Industrial Property (“Paris Convention”) was established in Paris in 1883. It is one of the first treaties in the field of intellectual property rights. The Act of Paris Convention has been revised many times after its inception. Presently, the Stockholm Act, 1967 of the convention is under force. Currently, there are 176 countries member to the Paris convention. India signed Paris Convention on September 7, 1998, and it entered into force on December 7, 1998¹⁶.

There are three main categories of provisions under the Paris Convention¹⁷:
(i) National treatment: According to this provision, each member country of the convention must grant the same protection to the industrial property (patents, trademarks, industrial designs, utility models etc.) of the nationals and citizens of the other member countries that it grants to its own nationals. Therefore, the rights of the foreigners with respect to the industrial properties will not be discriminated against in any way.
(ii) Right of priority: When a patent application (“the first application”) is filed in one of the member countries to the convention, and subsequently
another application(s) claiming the same or substantially the same invention is/are filed in other member country(ies) within 12 months of filing the first application, then the subsequently filed application(s) will be regarded as if it/they had been filed on the same day as the first application. The filing date of the first application is termed as the “priority date”. Under this rule, the priority date and not the national filing date, is used for assessing the patentability of the invention. Therefore, a later filing of the application in the other member country does not destroy novelty of such later filed application.

(iii) **Common rules:** The convention has laid down few common rules which all the member countries are obliged to follow. Some important common rules for patents are -

- Grant of a patent in one member country does not require any other member country to grant a patent for the same invention (“independence of patents”). Moreover, a patent cannot be refused, invalidated or terminated in other member countries on the ground that the patent for the same invention has been refused / invalidated/ terminated in one member country.

- The inventor has the right to get his/ her name mentioned as such in the patent.

- The member country may not refuse the grant of a patent and/ or invalidate a patent based on the ground that certain restrictions/ limitations to the sale of such patented product or product obtained by the patent process applies in the country.

- To prevent the abuse of patent rights, the member country may make regulations for the grant of compulsory license under certain conditions.
1.2.2.2 TRIPS agreement

TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement is a comprehensive international agreement on intellectual property administered by the World Trade Organization (WTO). WTO is an international organization which regulates the world trade. It was established on January 1, 1995 replacing the earlier trade agreement viz. the General Agreement on Tariffs and Trade (GATT). The WTO agreements cover various aspects of the international trade including goods, services and intellectual property. TRIPS which is a part and parcel of WTO, has prescribed the intellectual property rules for the world trading system. India became member of WTO and signed TRIPS on its inception date i.e., January 1, 1995.

TRIPS has covered a wide range of areas of intellectual property including patents, industrial designs, geographical indications (GIs), trademarks, copyright, integrated circuits layout-designs (topographies) and undisclosed information, including trade secrets.

The main features of TRIPS agreement are:

(a) Standards: TRIPS has prescribed the minimum standards of protection to be provided by the member countries with respect to each of the intellectual property areas covered under the agreement. The standards of protection include (i) subject matter to be protected; (ii) rights of the IP owners and permissible exceptions to those rights; and (iii) the minimum duration of protection. TRIPS also mandates that all the member countries to TRIPS shall also comply with the provisions of the Paris Convention, the WIPO Convention and the Berne Convention for the Protection of Literary and Artistic Works.

(b) Enforcement: TRIPS has laid down certain general principles relating to the civil, administrative and criminal procedures and remedies for the enforcement of IPRs by the member countries.
(c) **Dispute settlement:** TRIPS has set the procedure for prevention and settlement of disputes pertaining to the subject matter of the agreement between the WTO members.

The text of the TRIPS agreement comprises total seven parts consisting of 73 articles. Standards concerning the availability, scope and use of patents are provided under the Section 5 (articles 27-34) of the Part II of the agreement. Salient provisions relating to patents under the TRIPS agreement are described below.\textsuperscript{21,22}

(i) **Patentable subject matter:** The member countries shall make the patents available for all kind of inventions (products/processes) in all fields of technology, subject to the criteria of novelty, inventiveness and industrial applicability. No discrimination with respect to the place of invention, field of technology or requirement of local manufacturing of the patented product shall be made during the grant and enforcement of the patent rights in the country (Article 27.1).

(ii) **Permissible exclusions to patentable subject matter:** Members may exclude from patentability (a) the inventions contrary to public order or morality; (b) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and (c) plants and animals as a whole (other than micro-organisms), and essentially biological processes (excluding non-biological and microbiological processes) for the production of plants or animals. The member countries must however provide protection of plant varieties either by patents or by a *sui generis* system (Article 27.2 & Article 27.3).

(iii) **Rights conferred:** A patent shall confer on its owner the exclusive rights to prevent third parties from an unauthorized making, using, offering for sale, selling, or importing the patented invention. Patent owners shall also have the right to assign, license or transfer the patent rights (Article 28). A limited exception to the exclusive rights of the patent owners may be
allowed, provided that such exceptions do not unduly obstruct the normal exploitation of the patent or harm the legitimate interests of the patent owner (Article 30).

(iv) **Conditions on patent applicants:** The patent applicant shall fully and clearly disclose the invention enabling a person skilled in the art to carry out such invention. Applicant may be required to disclose the best mode to carry out the invention known to him. The applicant may also be required to provide information related to the corresponding foreign applications (Article 29).

(v) **Other use without authorization of the right holder:** Compulsory licensing and government use of patented invention without authorization of the patent owner are allowed on certain grounds. It must be however, subject to protecting the legitimate interests of the patent owner (Article 31).

(vi) **Revocation/ forfeiture of patent:** The member country shall provide for the procedure for judicial review of any decision of revocation/ forfeiture of patents.

(vii) **Term of protection:** Minimum term of patent protection shall be twenty years counted from the patent filing date.

(viii) **Burden of proof:** In a suit concerning infringement of a process patent, the judicial authorities of the member country have the power to order the defendant to prove that the process used by him to obtain an identical product is different from the patented process.

### 1.2.2.3 Patent Cooperation Treaty (PCT)

PCT is a treaty for international cooperation in the field of patents. It is administered by the World Intellectual Property Organization (WIPO). PCT was concluded in 1970. India signed PCT on September 7, 1998, and it entered into force on December 7, 199823.
PCT provides a route of filing an “international patent application” to get patent protection for an invention simultaneously in a large number of countries members to the PCT. An applicant is required to file only one “international patent application” in one language at one patent office (the “receiving office”) by paying one set of fee. Such application would have effect in all the PCT contracting countries which the patent applicant selects (“designates”) in his application.

A PCT application can be filed either as the “first application” or within 12 months of filing the first application, claiming priority of the earlier filed application. After filing the PCT application, an international prior art search is carried out on the claimed invention by the “International Search Authority (ISA)” selected by the applicant. ISA provides result of the search in an “international search report” to the applicant. The international application is published (“international publication”) after 18 months from the priority date. After receiving the search report the applicant may request for an “International Preliminary Examination (IPE)” of the application by filing a “demand” (with appropriate fee) in which the designated countries are “elected”. IPE is conducted by an “International Preliminary Examination Authority (IPEA)”. IPEA after conducting the preliminary examination provides to the applicant a non-binding opinion in the form of a report on the patentability of the claimed invention. The applicant after receiving the report of IPEA, gets a chance to amend its application in order to take into consideration the prior art references cited in the reports of ISA/ IPEA. The report of IPEA also provides the applicant a stronger basis for calculating the chance of getting the patent on the claimed invention. If the applicant sees no likelihood of patent grant at this stage, he may withdraw the application. In such a case still, it saves a great expense for the applicant, as the applicant gets assessment of his application for a large number of countries by paying only one set of fee.
Above international phase of PCT filing lasts for 20-30 months from the priority date, after that the application enters into the national phase (if the applicant decides to continue the procedure). In the national phase, the applicant is required to pay the prescribed patent filing/examination fee for each of the designated/elected countries where the applicant decides to pursue the application. Under the national phase, the application is then examined separately by the patent offices of each of the designated/elected countries through their normal national procedures. The national phase ends by either rejecting or granting the patent by the individual patent office. PCT therefore, does not provide for the grant of any “international patent”, however it provides for a route for filing an “international patent application”.25

1.2.2.4 Budapest treaty

The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (“Budapest treaty”) is a special agreement under the Paris Convention, which entered into force on August 9, 1980. India signed the Budapest treaty on September 17, 2001, and it entered into force on December 17, 2001.26

When an invention involves a new biological material e.g. microorganisms, the applicant is required to deposit a sample of such biological material to meet the full disclosure requirement under the patent law. However, the patent offices are not equipped to handle and preserve the biological materials, therefore, such materials are to be deposited at authorized scientific institutions e.g., culture collection centres. When an applicant files a patent in several countries, it becomes extremely difficult for him to transport and deposit the samples of biological material to the scientific institutions of each of those countries. Budapest treaty provides a uniform international deposit system for biological materials for the purposes of patent procedure. Under the treaty, single deposition of the biological material at the recognized
international depositary authority (scientific institution) of any one of the member country, is recognized by and is sufficient for the purpose of patent procedure before the patent offices of all the member countries. Budapest treaty, therefore, makes the procedure of deposition of biological material very easy, safe and economic\textsuperscript{27}.

\textbf{1.2.2.5 Patent law treaty}

“Patent Law Treaty” (PLT) is a new agreement in the field of patents, administered by the World Intellectual Property Organization (WIPO), concluded on June 1, 2000. PLT aims to harmonize formal procedures relating to filing and processing of patent applications in the contracting states\textsuperscript{28}. PLT deals with harmonizing regulations pertaining to assignment of filing date of the patent applications, forms and contents of the application, time limits for the payment of fees, and certain other procedures before the national/ regional patent offices. At present, India has not signed the Patent Law Treaty.

In 2001, WIPO proposed another agreement viz. “Substantive Patent Law Treaty” (SPLT), which aims to harmonize the substantive requirements under the patent laws such as criteria of patentability, unity of invention, sufficiency of disclosure, claim drafting and claim interpretation etc. SPLT has not finalized yet, and is currently under negotiation\textsuperscript{29}.

Both PLT and SPLT are directed towards harmonizing the patent law and regulations across the globe. Harmonization of patent system is associated with both advantages and disadvantages. It has been argued that patent law harmonization will benefit the developed countries more as compared to the developing counties, since patent law harmonization may take away the TRIPS flexibilities currently available under the patenting system. Further, it is doubted that patent law harmonization will make the patent system more
stringent with less autonomy for decision making with respect to patent regulations at the national level. Therefore, it is recommended that during the discussion for patent law harmonization, the developing countries should not compromise with the available TRIPS flexibilities such as compulsory licensing, bolar provision etc. For India, it is suggested that before joining patent law harmonization drive, India should first focus on encouragement of R&D and strengthening the infrastructure facilities for patenting in the country. 

30-32
1.3 Review of literature

The review of literature presents below the view points of various organizations and persons on different issues concerning India’s patent regulations and IP environment. Further, few steps taken by the Indian government for strengthening the IP framework in India are also highlighted here.

1.3.1 IP environment in India and its effect on the country’s economy

Global Intellectual Property Centre (GIPC), U.S. released the third edition of GIPC International IP Index in February, 2015. India has been ranked at the second-to-last (29th) position in this Index. Based on the national IP environments the index evaluated and ranked 30 countries of the world which together comprise around 80% of the global Gross Domestic Product (GDP). In the earlier editions of the index also India was ranked at the last position.

The index enlisted restrictive patentability criteria; broad compulsory licensing provisions; unavailability of patent term restoration; absence of the patent linkage system; poor patent enforcement mechanism and India not being a member of Patent Law Treaty as the major weaknesses in India’s IP environment.

Earlier, in 2013, GIPC published another report entitled “India: International Outlier on IP”. The report presented a review on the framework for IP rights in India and its influence of country’s economic development. As per this report Indian economy performed noticeably below as compared to the other BRIC (Brazil, Russia, and China) and middle-income countries since 1980s. The report contended that India’s weak IP environment is the main responsible factor for a consistently poor annual FDI in the country, and thus it is harming country’s economy. The report further indicated that if India adopts stronger policies and framework for IP rights, the FDI would increase significantly.
1.3.2 Innovation climate in India
Cornell University (U.S.), INSEAD Business School (France) and WIPO jointly published “The Global Innovation Index (GII), 2015”\(^\text{35}\). The GII is an annual publication that ranks countries and economies in terms of their environment to facilitate innovation and their innovation outputs. In this Index, India is ranked at 81\(^{\text{th}}\) rank, behind many other developing countries such as China (29\(^{\text{th}}\) rank), Malaysia (32\(^{\text{nd}}\) rank), Russia (48\(^{\text{th}}\) rank), Thailand (55\(^{\text{th}}\) rank), and Brazil (70\(^{\text{th}}\) rank).

1.3.3 Effect of India’s patent/ IP regulations on the business of foreign companies in India
European Commission raised its concern over the constraints in getting effective patent protection in India and stated that these constraints are detrimental to the business of European companies in India\(^\text{36}\). The commission enumerated restrictive patentability criteria; difficulties in patent enforcement; and extremely broad criteria for granting compulsory licences/ for the revocation of patents as the major constraints in India. The United States International Trade Commission also similarly alleged that India’s current IP policy is inducing barrier to trade and is an obstacle in the business environment in India for the U.S. companies\(^\text{37}\).

Paul Herrling, Chairman, Novartis Institute of Tropical Diseases, Singapore commented on Indian Supreme Court’s decision of rejecting patent on the drug Gleevac\(^\text{38}\). Paul said that this decision will make India less attractive for innovative pharmaceutical companies since it is much easier in India to make cheaper copies of the drugs. Paul further added that India will also not be the first choice as an innovation research centre for his company.

Manisha Desai, Assistant General Patent Counsel at Eli Lilly & Company, raised concern over India’s IP policies by stating that while protecting the
interest of the domestic industry the Indian government is unduly impeding innovation based pharmaceutical companies in obtaining and enforcing their patent rights. Desai indicated the policies of the Indian government as anti-IP.

In 2013, 170 members of U.S. Congress wrote a letter to President Barack Obama complaining that India’s IP policy is harming the business of U.S. companies in India. The letter specifically criticized about IP issues affecting biopharmaceuticals. The members pointed out that the patents on a variety of life saving drugs of several U.S companies were inappropriately revoked in India. Further, the members alleged that the grant of compulsory license in the Naxavar case by the Indian government was improper.

1.3.4 Issues concerning Section 3(d) in the Indian Patents Act

In 2006, Assistant Controller of Patents and Designs refused the pharmaceutical company Novartis to grant a patent for β-crystalline form of the drug Imatinib mesylate, on the grounds that the claimed form lacked novelty, was obvious, and was non patentable under Section 3(d) of the Indian Patents Act. The Assistant Controller’s decision was upheld later at IPAB in 2009 and by the Supreme Court in 2013.

Organization of Pharmaceutical Producers of India (OPPI), argued that the Section 3(d) in the Indian Patents Act is inconsistent with the Article 27 of the TRIPS agreement. According to OPPI, Section 3(d) violates the non-discrimination principle provided under Article 27 by putting additional hurdles for patentability on inventions specifically relating to drug/chemical compounds. Further, OPPI stated that TRIPS Article 27 provides a non-extendable list of subject matter which can to be excluded from patentability by the member countries, however the subject matter excluded from
patentability by Section 3(d) i.e., new forms of the know substances is beyond the said list of Article 27.

1.3.5 Grant of compulsory license in India

In 2012, the Controller of Patents\textsuperscript{43} issued the first compulsory license (CL) for patents in India. The CL was issued to Natco Pharma Ltd. in patent number 215758. The patent is granted to Bayer Corporation for the drug Sorafenib tosylate sold under the brand name Nexavar. This drug is indicated in Renal Cell Carcinoma (kidney cancer) and Hepatocellular Carcinoma (liver cancer). Bayer challenged this decision sequentially at Intellectual Property Appellate Board (IPAB), Bombay High Court and finally at the Supreme Court. In December 2014, the Supreme Court upheld the compulsory license issued to Natco and concluded the legal proceedings on the case.

United States International Trade Commission and Office of the United States Trade Representative in their reports stated that Indian government has promoted compulsory licensing in its “National Manufacturing Policy” as a mechanism to effectuate technology transfer in certain sectors, which indicates that the government is using compulsory licensing merely as a tool to achieve its industrial policy goals rather than for protecting public health in the country\textsuperscript{44,45}.

SA Teresa, the Deputy Under Secretary of Commerce for Intellectual Property and the Deputy Director of the United States Patent & Trademark Office (USPTO) appeared before the U.S. House of Representatives and alleged in her testimony that the compulsory license issued in the Nexavar case by India was in violation of the TRIPS agreement\textsuperscript{46}.

S Singham, Managing Director, Competitiveness & Enterprise Development Project at Babson Global, U.S. criticized compulsory licensing provision in
India by stating that as provided in the Indian Patents Act, compulsory licences cannot be used as a substitute for the antitrust law or as a market mechanism. Singham further asserted that a dispute settlement case could be filed against India at WTO for handling compulsory license in an inappropriate manner in the Naxavar case47.

1.3.6 Patent opposition

Reports issued by the United States International Trade Commission and Office of the United States Trade Representative criticized India’s current patent opposition provision44,45. Reports mentioned that the current patent opposition procedure in India causes undue delay in the patent grant and is a burden on the patent applicants.

1.3.7 Section 8 requirement in the Indian Patents Act

Organization of Pharmaceutical Producers of India (OPPI) commented on Section 8 requirement of the Indian Patents Act relating to the information and undertaking regarding foreign applications42. According to OPPI this requirement is unnecessarily burdensome and unduly targets the foreign patent applicants. Also, penalty, i.e., revocation of the patent for failure to comply with this section is extreme as compared to other countries.

1.3.8 Reporting of working of patents in India

GV Sheth, an Indian Patent Agent reported that the requirements related to the statement of working of patents in India are ambiguous and not clear48. Sheth stated that as per the Section 146(2) of the Indian Patents Act, every patentee/licensee is required to file a statement of working of the patented invention on Form 27 each year. The provision requires 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.

1.3.9 Measures for strengthening patent/ IP regulations in India

The Prime Minister of India, Narendra Modi inaugurated the first “Global Exhibition on Services” in New Delhi on April 23, 2015\textsuperscript{49}. The Prime Minister in his inaugural speech said that the government is working towards strengthening intellectual property rights (IPR) regime in the country. He further added that “if we can convince the world about the robustness of our IPR, there is a huge scope for our creative industry to flourish”.

In 2015, Department of Industrial Policy and Promotion (DIPP), Government of India released a press note stating several measures taken by the government of India to improve the IP environment in the country for boosting the “Make in India” campaign\textsuperscript{50}. The measures taken by the government include modernization of IP administration, ease of access of information through patent office website, e-filing facilities, fee rebate on e-filing and for MSMEs, ratification of the Madrid protocol, IPR awareness programmes and India being recognized by WIPO as an international search and preliminary examining authority.

Department of Industrial Policy and Promotion (DIPP), Government of India released the first draft of the “National IPR Policy” in 2014\textsuperscript{51}. The draft emphasized on the need to implement a new law on utility model patents (petty patents), which has been successfully applied in many countries but is not available currently in India. Utility models allow patenting of the inventions which are novel, utilitarian and inventive in their own spheres, however may not satisfy the criteria of patentability under the current Patents Act. Utility models are of great benefit for the Micro, Small and Medium Enterprises (MSMEs) and for the companies working in the unorganized/
informal sectors. MSMEs comprise about 45% of the total manufacturing output however they hold only limited IP assets. The draft further emphasized on the need to modernize and strengthen IP administration, and to strengthen the enforcement and adjudicatory mechanisms in India.
1.4 Research envisaged

The review of literature revealed that various questions/concerns have been raised in recent past over the current patent regulations in India, particularly with respect to patenting of pharmaceuticals. Many shortcomings in the Indian patenting system have been pointed out by the pharmaceutical companies, manufacturer organizations, IP professionals, foreign government agencies/officials etc. It is argued that India has not been able to adhere to the internationally accepted best practices in the field of IP. It is further contended that India has a weak national IP environment which is harming country’s economy. Concerns have been raised particularly with respect to criteria of patentability, patent opposition, compulsory licensing provisions, and patent administration and patent enforcement mechanisms in the country. In order to examine India’s positions on patenting of pharmaceuticals and to find out areas of improvement in the Indian patenting system, there exists a need to review the current regulations for patenting of pharmaceuticals in India, and to compare it with the relevant regulations in the developed countries such as US and Europe, and in developing country like China. Based on the comparison, measures to strengthen patent regulations in India shall be proposed.
1.5 Aim of the research work

The main aim of the present research work is to find out areas of improvement in the existing Indian regulations for patenting of pharmaceuticals based on a comparison of the Indian patent regulations with the relevant regulations in U.S., Europe and China, and to propose measures to strengthen the Indian regulations.

To fulfil the aims/ objectives of the present research, patent laws of U.S., Europe, China and India shall be studied thoroughly and the Indian regulations for patenting of pharmaceuticals will be compared with the patent regulations of U.S., Europe and China. For collecting empirical data, a research questionnaire will be designed based on various questions/ concerns raised over the current patenting system in India at national and international fronts. Responses will be collected online as well as in-person from the professionals and experts working in the IP and pharmaceutical fields. Further, important case laws will also be reviewed in this context. Based on the comparative study, review of the case laws and analysis of the collected empirical data, suggestions for strengthening the patent regulations in India will be proposed.