Patenting, pharmaceuticals comparative study laws US Europe China India

A.S.Prasanna [1], K.Umasankar[2], Praveen Kumar[*3], M.Kishore Babu[4]

1. Prasanna.AS, Krishna Teja Pharmacy College, Tirupati.asprasanna25@gmail.com
2. Professor, Dept of Pharmaceutics, Krishna Teja Pharmacy College, Tirupati. Andhra Pradesh.umasankar83@gmail.com
3. Associate Professor, Dept of Regulatory affairs, Krishna Teja Pharmacy College, Tirupati. Andhra Pradesh.
jaldupraveen@gmail.com
4. Principal, Krishna Teja Pharmacy College, Tirupati.

Abstract

Patenting system plays an important role in the growth of the industries. More particularly, patents have profound effect on the activities of innovation driven industries such as the pharmaceutical industry. History of patent law in India dates back to 19th century when the first Patents Act was enacted under the British rule. After India's independence, the Patents Act, 1970 came into force which reflected the concerns of developing countries in the area of patenting. After India's signing of TRIPS agreement in 1995, major changes were introduced in the Act to make it compliant with norms of the agreement. However, the current Indian patent regulations have been under constant criticism particularly with respect to patenting of pharmaceuticals. It is argued that India has not been able to adhere to the internationally accepted best practices in the field of patents. This thesis is an endeavour to analyze India's position on the patenting of pharmaceuticals and to find out areas of improvement in the existingIndian patent regulations.

Keywords: Patent, pharmaceuticals, patent law, comparative study, India, U.S., Europe, China

Introduction

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, copy rights 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

(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.

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 3rd largest in the world by volume and 13th in value. Indian generics account for 20% (in terms of volume) of the total global exports of generics. Indian drugs are exported to around 200 countries in the world including countries with highly regulated markets such as USA and Europe.

Historical perspective and conceptual framework

Brief history of Indian patents law

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.

Type of patent applications

Type of patent applications that can be filed in India -

1. Ordinary application: Application not claiming priority of any foreign application, and filed directly at the Indian Patent Office.
2. Convention application: An application filed under the Paris Convention which claims priority of a foreign patent application.
3. PCT application: International patent application filed under the Patent Cooperation Treaty (PCT).
4. Divisional application, which can result from division of a filed patentapplication.
5. Patent of addition: It can be filed subsequent to the filing of a patent application, for an improvement or modification in the invention.

Persons entitled to apply for patents

Any of the following persons can file a patent application in India either alone or jointly with each other-

- a person who claims himself the true and first investor of the invention;
- an assignee of the person who is claiming himself the true and first investor of the invention

- The legal representative of a deceased person who was entitled to make such an application before his/ her death.
-

Patent offices and their jurisdiction

Indian patent offices are situated at four locations viz. Kolkata, Delhi, Chennai and Mumbai. The patent specification along with the prescribed form and fee shall be filed with the patent office having the appropriate jurisdiction. The patent application can also be filed online at the Indian patent office website i.e., http://www.ipindia.nic.in/.

Overview of patent grant procedure in India

Patent application filing at Indian patent office*

↓

(Assigning of filing date and patent application number)

Publication**

↓

(After 18 months from the filing date)

Pre-grant opposition

↓

(From the date of publication till patent rejection/ grant)

Request for examination

↓

(Within 48 months from the filing date)

Examination

↓

Issue of First Examination Report (FER)

↓

Applicant's response to the FER

↓

Patent application rejection[#]/ patent grant[##]

↓

Post-grant opposition

(Within 12 months of the patent grant)

Overview of patent grant in India

* Application can be filed either with provisional or complete specification; complete specification shall be filed within 12 months of filing the provisional specification; only complete specification shall be published (Section 9).

** Applicant can make request in Form-9 for publication earlier than 18 months (early publication); the controller shall publish such application as soon as possible (Section 11A (2); Rule 24A).

Provisions of the Indian patent law were compared with the relevant provisions of the patent laws in U.S., Europe and China.

Governing laws/ regulations

Table: provides details about the governing patent laws/ regulations in U.S., Europe, China and India.

Governing patent laws/ regulations

Country / Parameter	U.S.	Europe	China	India
Law	U.S. Patent Law (35 U.S.C.); as amended by Leahy-Smith America Invents Act (AIA), 2011	European Patent Convention(EPC) - 15th edition, 2013	Patent Law of the PRC, 1984; as amended in 1992, 2000 and 2008	Patents Act, 1970; as amended in 1999, 2002. and 2005
Rules/ Regulations	U.S. PatentRules (37 C.F.R); as updated in November,2015	Implementing Regulations to the EPC, 2014	Implementing Regulations ofthe Patent Lawof the PRC, 2001; as amended in 2002 and 2010	Patents Rules, 2003; as amended in 2005, 2006, 2012 and 2014

Discussion:

U.S., Europe, China and India have their respective patent laws and regulations. China and India amended their patent laws to fulfil the obligation of TRIPS agreement. India in 2005 and China in 2008 made their Patent Acts TRIPS compliant.

Patentable subject matter and criteria of patentability

Subject matter eligible for patent grant and conditions of patentability are compared in Table.

Comparison of patentable subject matter and criteria of patentability

Country / Parameter	U.S.	Europe	China	India
Patentable subject matter	Invention or discovery of a new & useful process/ machine/ manufacture/ composition of matter or improvement thereof	Invention which is new, involve an inventive step; & industrially applicable, belonging toany field of technology	Inventions inthe form of new technical solution or improvementto a product/ process	New product or process involving an inventive step and capable of industrial application
Criteria of patentability	Novelty; Non-obviousness; Usefulness	Novelty; Inventivestep; Industrial application	Novelty; Inventivestep; Practical applicability	Newness; Inventivestep; Industrial applicability

Discussion:

All the countries viz. U.S., Europe, China and India grant patents for inventions which fulfil the three conditions of patentability viz. newness/ novelty, inventive step/ non-obviousness, and industrial applicability/ usefulness. This in compliance with the TRIPS Article 27, which states that patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

Patentability of polymorphs/ new forms

Comparison in the patentability of polymorphs/ new forms is provided inTable.

Comparison in the patentability of polymorphs/ new forms

Country / Parameter	U.S.	Europe	China	India
Specific restrictions on the patentabilityof polymorphs/new forms in the governing law/ rules	No specific restrictions	No specific restrictions	No specific restrictions	Under Section 3(d)of the Patents Act,to be patentable a new form ofthe known substance must show enhanced efficacy as compared to the existing substance
Regulationsby case laws/ patentprosecution/ examinationguidelines	The new form shall not be a result of routine "experiment-tation"; it shall not be "obvious to try"; and it shall not be "inherently disclosed" in the prior art; "unexpected results" can be used to rebut obviousness	The polymorph shall merely not provide only the "obvious advantages" ofa crystalline material over the amorphous form; in the absence of any "technical prejudice" and "unexpected property" it cannot be regarded as inventive	An "unexpected effect" of the claimed polymorph shall be demonstrated; "obvious advantages" of the polymorph such as better stability is not sufficient to establish the inventive step	Term "efficacy" in Section 3(d) means "therapeutic efficacy"

Discussion:

In India, specific restrictions on the patentability of polymorphs and other new forms of a known drug substances have been put through the Section 3(d). Although, the patent laws in U.S., Europe and China do not explicitly put restrictions on the patentability of polymorphs/ new forms, however limitations in terms of raised standard of inventive step/ obviousness and novelty requirements have been put under the case laws/ patent examination guidelines in these countries. Indian patent law requires that for being patentable, a new form shall be more "efficacious" than the existing known substance. In the Novartis-Glivec case, the supreme

court of India has provided the meaning of the term “efficacy” in the Section 3(d) as “therapeutic efficacy”. Some authors however have suggested that the meaning of the term “efficacy” may be defined in the Patents Act in a broader way to encompass other relevant aspects such as decreased toxicity or side effects, increased bio- availability or improved physicochemical properties.

Duty to disclose information regarding foreign applications Comparison of the provision regarding duty to disclose information regardingforeign applications is presented in Table.

Comparison of the provision regarding duty to disclose information regarding foreign applications

Country / Parameter	U.S.	Europe	China	India
Provision under thelaw	All information material to the patentability of the invention shall be disclosed to USPTO	Copy of the results of prior art search/ patent examinations (priority search reports) shall be provided to EPO	Copy of the results of prior art search/ patent examinations (priority search reports) shallbe provided to SIPO	Detailed particulars of the corresponding foreign patent application(s)must be submitted to the Indian Patent office from time totime
Case laws	Information is material to the patentability if it establishes a	---	---	Conflicting decisions; IPAB held that failure to comply due to

Discussion:
All the countries viz. U.S., Europe, China and India require the applicants to disclose information regarding corresponding foreign patent applications. However, regulations in India in this context seem to be much more strict and difficult to comply with. In the U.S., the applicant’s duty is limited to submit any information that is material to the patentability of the claimed.

Comparison of compulsory licensing provisions in Europe and India

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

Discussion:

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, as provided in the European regulations.

Comparison of compulsory licensing provisions in China and India is providedin Table

Comparison of compulsory licensing provisions in China andIndia

Ground/ parameter for compulsory license (CL)	Provision in Chinese Patent Law	Provision in Indian Patents Act
Non-working of the patentby the patentee	Article 48	Sec. 84(1)(c)
Anti- competitive practiceby the patentee	Article 48	Sect. 83(f)
Circumstances of national emergency or extreme urgency	Article 49	Sec. 92
Public health crises	Article 50	Sec. 92

Based on the findings of the present research work, following measures are proposed for strengthening the patent regulations in India.

Patent office administration

In order to improve the efficiency of patent office administration in India, measures such as hiring more patent examiners, training of the officials, improving working conditions of the patent examiners[240-242] and digitalization of the patent databases and procedures at the patent offices are required to be taken Encouragement of patent filing by Indian citizens

To encourage patent filing by the Indian citizens there is a need to increase awareness about the benefits/ role of patents and IPR in India for which more number of patent/ IPR awareness workshops, seminars, camps and training programmes may be organized on regular basis by both the state and central governments in India. As adopted in China, representative offices of the Indian Patent Office may also be opened in all state capitals and district headquarters in India. Indian government may provide subsidy in the patent filing/ examination fee to the Indian applicants to encourage patent filing by them (*See* Where to file the patent application? (2.4.4) in 2.4: Patent law in China).

Patentability of polymorphs/ new forms

In the Novartis Glivec case, the supreme court of India provided meaning of the term "efficacy" as "therapeutic efficacy". However, it has been argued that it is a very restrictive interpretation of the term "efficacy.

Summary

U.S., Europe, China and India grant patents for inventions fulfilling the three general criteria of patentability (as per TRIPS Article 27) viz. newness/ novelty, inventive step/ non-obviousness, and industrial applicability/ usefulness. Indian patent law puts specific restrictions on the patentability of polymorphs and other new forms of the known drug substances through Section 3(d). A raised standard of inventive step and novelty requirements for the same have been set under the case laws/ patent examination guidelines in U.S., Europe and China.

To felicitate patent filing by the Chinese citizens, SIPO has established its representative offices at all state capitals and district headquarters. Few differences exist in the patent prosecution in the U.S., Europe, China and India. The U.S. patent law provides the option to opt-out of the publication of the patent application in certain cases. This option is not available in Europe, China and India. During patent prosecution, EPO issues a search report & opinion on patentability on the claimed invention; however, U.S., China and India do not have such provision. Patent laws in U.S., Europe and China provide various procedures to expedite the patent examination, whereas, no such procedures are currently available in India. Option for supplemental examination after the grant of a patent is provided only under the U.S. law. Continued examination/ re-examination is possible in the U.S. and China but not in Europe and India.

Conclusion

The present research work was aimed to find out areas of improvement in the existing Indian regulations for patenting of pharmaceuticals. The patent laws of India, U.S., Europe and China were studied thoroughly and Indian regulations were compared with the patent regulations of U.S., Europe and China. Empirical data was collected through research questionnaire. Important case laws were also reviewed. 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 were proposed.

REFERENCES

1. International Chamber of Commerce (ICC) and World IntellectualProperty Organization (WIPO). Making intellectual property work forbusiness: A handbook f chambers of commerce and business associations setting up intellectual property services. Available at: http://www.wipo.int/edocs/pubdocs/en/intproperty/956/wipo_pub_956.pdf (accessed 13 February, 2014)
2. Economic benefits of the patent system. Available at: http://www.alrc.gov.au/publications/2-patent-system/economic-benefits- patent-system (accessed 16 February, 2014)
3. Advantages & Disadvantages of Patents. Available at: http://1degreebio.org/blog/?bid=201 (accessed 16 February, 2014)
4. Controller General of Patents, Designs, Trademark and GeographicalIndication, Government of India. Annual Report 2013-2014. Available at: http://ipindia.gov.in/cgpdtm/AnnualReport_English_2013_2014.pdf (accessed 18 October 2015)
5. Nobel Laureates Spotlight India‟s Invention Problem. Available at: http://www.indiaspend.com/cover-story/nobel-laureates-spotlight-indias- invention-problem-61176 (accessed 25 January, 2016)
6. World Intellectual Property Organisation (WIPO). Patent CooperationTreaty Yearly Review. Available at: http://www.wipo.int/edocs/pubdocs/en/wipo_pub_901_2015.pdf (accessed19 July, 2015)
7. Pharmaceuticals: India in Business, Ministry of External Affairs, Government of India. Available at: http://indiainbusiness.nic.in/newdesign/index.php?param=industryservices _landing/347/1 (accessed 19 January, 2016)
8. India Pharma 2020: Propelling access and acceptance, realising truepotential. McKinsey & Company, Inc. 2013. Available at: http://online.wsj.com/public/resources/documents/McKinseyPharma2020 ExecutiveSummary.pdf (accessed 17 March, 2014)
9. Indian pharmaceutical industry likely to touch USD 55 bln by 2020: study. Available at: http://www.assocham.org/newsdetail.php?id=5406 (accessed 21 January 2016)
10. Business Standard. Indian pharma firms must innovate in face of genericdrugs

slowdown. Available at: http://www.business-standard.com/article/news-ians/indian-pharma-firms-must-innovate-in- face-of-generic-drugs-slowdown-115031601168_1.html (accessed 21January 2016)

11. Draft Manual of Patent Practice and Procedure the Patent Office, India.Available at: https://www.indiaoppi.com/sites/default/files/PDF%20files/DraftPatent_ Manual_2008.pdf (accessed 16 September 2014)
12. History of Indian Patent System. Available at: http://ipindia.nic.in/ipr/PatentHistory.htm (accessed 16 September 2014)
13. The Draft Patent (Amendment) Rules, 2015. Available at: http://www.ipindia.nic.in/IPActs_Rules/PatentRules_2015_E_29October 2015.pdf (accessed 13 December, 2015)
14. Paris Convention for the Protection of Industrial Property. Available at: http://www.wipo.int/treaties/en/ip/paris/ (accessed 09 November, 2014)
15. Summary of the Paris Convention for the Protection of Industrial Property(1883). Available at: http://www.wipo.int/treaties/en/ip/paris/summary_paris.html (accessed09 November, 2014)
16. The GATT years: from Havana to Marrakesh. Available at: https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm (accessed 18 May, 2014)
17. Intellectual property: protection and enforcement. Available at: https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm(accessed 18 May, 2014)
18. Report on Differences Of IPR Laws between Europe & India forEuropean SMEs How To Tackle Them? Available at: http://www.indiaitaly.com/REP_Differences%20of%20IPR%20Laws_EU

i. %20&%20India_Web.pdf (accessed 04 October, 2015)

19. Agreement on Trade-Related Aspects of Intellectual Property Rights. Available at: https://www.wto.org/english/docs_e/legal_e/27-trips.pdf (accessed 18 May, 2014)
20. Trade-Related Aspects of Intellectual Property Rights. Available at: https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/8_bgd_trips_89_ e.pdf (accessed 18 May, 2014)
21. Contracting Parties: Patent Cooperation Treaty. Available at: http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=6 (accessed 12 February, 2015)
22. Summary of the Patent Cooperation Treaty (PCT) (1970). Available at: http://www.wipo.int/treaties/en/registration/pct/summary_pct.html (accessed 12 February, 2015)
23. International Treaties and Conventions on Intellectual Property (Chapter 5). In: WIPO Intellectual Property Handbook: Policy, Law and Use. Available at: