IOSR Journal of Pharmacy and Biological Sciences (IOSR-JPBS)
e-ISSN:2278-3008, p-ISSN:2319-7676. Volume 12, Issue 5 Ver. II (Sep. – Oct. 2017), PP 01-06
www.iosrjournals.org

To Study and Compare Patent Law Pertaining To Pharmaceuticals in India, China and US

Pise Shilpa A.*[1], Pise Ajay G. [2], Yeole P.G. [3]
[1]*PhD Scholar, Institute of Pharmaceutical Education and Research (IPER), Borgaon (Meghe), Wardha 442001, MS, India*
[2]*Associate Professor, Dadasaheb Balpande College of Pharmacy, Nagpur 440034, MS, India*
[3]*Pro-Vice Chancellor, R.T.M. Nagpur University, Nagpur 440033, MS, India*
Corresponding Author: Pise Shilpa A

Abstract
Objective: *To assess and draw inferences of patent law in India, China and US in Pharmaceuticals*
Research methodology: *This study is based on secondary Data collection from authentic websites of Government agencies, Magazines, Scientific Journals, and News Bulletins.*
Results*: Patent laws of India, China and US are compared with special reference to field of pharmaceuticals. This study focus on some patentability aspects and criteria for pharmaceuticals in mentioned countries*
Discussion: *The study shows that pharmaceuticals are very crucial for patenting as patent increases cost of life saving drugs and deprive people of availing essential drugs.*
Conclusion: *From above study it is concluded that patentability criteria of novelty, non-obvious and utility in India, China and US is almost same and pharmaceuticals is very sensitive field for patenting as patent provides monopoly of marketing a drug and people in developing countries like India and China have to struggle to access basic drugs needed because of patents.*
Keywords: *pharmaceuticals, patents, patentability criteria*

Date of Submission: 01-06-2017 Date of acceptance: 13-09-2017

I. Introduction

Patent is exclusionary right given by the government to its inventor for a particular duration of time. Patent protects an invention, and grants to the owner the exclusive rights to use his invention for specified period of time.

Unlike computer and software industry, pharmaceutical industry is highly regulated because it ensures safety and efficacy of drugs sold to the consumers. The time period between filing of patent and launching a drug in market is very lengthy as clinical trials are needed to ensure the safety and efficacy of drugs[1].

According to one report of IBEF 2016, Indian pharmaceutical sector accounts for about 1.4 per cent of the global pharmaceutical industry in value terms and 10 per cent in volume terms. India accounts for 20 per cent of global exports in generics. In FY15, pharmaceuticals industry of India exported products worth USD15 billion and the exports are expected to reach USD40 billion by 2020. Indian healthcare sector, one of the fastest growing sectors, is expected to advance at a CAGR of 17 per cent to reach USD250 billion over 2008–20. The generics market is expected to grow to USD26.1 billion by 2016 from USD21 billion in 2015. India's generics market has immense potential for growth [2].

To protect the health of citizens, China's authorities did not give patent protection to avoid monopoly of pharmaceutical companies. So patent law 1984 excluded pharmaceuticals from patenting. But to enter WTO and to comply TRIPS, China revised its patent law and included pharmaceuticals and chemical products for patent protection. A product patent for a drug gives exclusive rights to patentee to manufacture, market, and sell the drug.

China is the second largest pharmaceutical market in the world and is expected to grow from $108 billion in 2015 to $167 billion by 2020, representing an annual growth rate of 9.1 percent. Pharmaceutical sales currently amount to 17 percent of total health expenditures. Generics dominate the total sales with 64 percent. Patented drugs amount to only 22 percent of total sales. Over the past decade, patented drug sales enjoyed strong, double digit growth rates [3].

When a new drug is launched in market, it is launched under a brand name. A company spends lot of time and money in conducting clinical trials to assess safety, efficacy, usefulness and launching one drug in market. The new drug is protected under patent by a pharmaceutical company and only that company can manufacture, sell or market that patented drug. The patented drug can be marketed for 20 years from date of

application and once this expires, the generic version of drug is launched. Evergreening of patent can be done by enhancing the efficacy of drug and filing a re-application. In US, evergreening of patents is common, but this practice hamper the launch of low cost drugs in market and people have to shed more money for patented drugs. The generic version of drug can be marketed only in cases:

The drug has become off-patent

In countries where the drug is not patent protected

The patent has been obtained illegally

The patent is invalid or unenforceable

Take a case of Novartis patent on leukemia drug, Gleevec. The company claimed that it is introducing new formulation and enhanced version of already existing drug and filed for patent. In US, the drug got the patent but Indian Supreme Court blocked the entry of new version and denied the patent. In US, the patient had to spend $70,000 for Gleevec, while in India it could cost $2500. Drugs at cheaper price is human right to medicine [4].

The companies use the tool of evergreening of patents to delay the launch of cheaper version. When a new drug enters the market, the profit can rise upto 90%. But if drug loses its patent, the first generic version is launched at 15-30% cheaper, but after expiration of 6 months, many companies come up with generic version, which increase the competition and decreases profit up to 90% [5]. The cost of development of one drug is approximately $2bn as per one estimate[6].

II. Literature Review

Wayne C. J. et.al. (2012) explicitly explained the different features of China Patent law and US Patent system. Recent changes in U.S. Patent law, as a result of the American Invents Act were also discussed. Till fourth draft of amendments proposed in China, methods for diagnosis or treatment of diseases; animal and plant varieties were not patentable in China while US allowed the patents for these. AIA has provision for patent term extension for pharmaceuticals while Chine yet to implement this. Wayne et.al. concluded that both China and US have healthy battle for patentable innovations and both countries need changes in laws and regulations to promote patent quality[7].

William J. Bennett (2014) studied Indian Pharmaceutical patent law and impact of TRIPS which brought product patents for pharmaceuticals. He analysed the Novartis case in India as Indian patent office rejected Glivec concluding that Glivec lacks novelty and inventiveness. The Indian Supreme court also rejected Glivec on same grounds. He concluded that India always encourage generic drugs and hinder growth of R&D[8].

Geeta Anand (2015) discussed India's patent fight with Big Pharma as many western companies have objected about India's narrow approach for patenting. The report of PricewaterhouseCoopers expected India's pharmaceutical sector to grow to at least $48.8 billion in sales by 2020 from $11 billion in 2012. Geeta A. explained in this study why India can not be so liberal in granting patents as cost of patented drugs is always out of reach of population, most population is uninsured while US is very liberal in granting monopoly for patent protection. 'Evergreening' of patents is common practice in US[9].

Chen Changhui (2015) discussed the proposed draft fourth amendment of Chinese patent law. The draft proposed to speed up patent infringement disputes and penalty for patent infringement increased. In recent years, the no. of patent applications filed in China have increased drastically but all the patents are not exploited and utilized effectively. So draft has proposed some legal safeguards for exploitation and utilization of patents. The patent filing facilities were also eased. Chen C. mentioned very systematic review of proposed fourth draft amendments. In current study we have discussed the amendments in Chinese patent law from the patent law enacted in China since 1984[10].

William A. et.al. analysed in their study about pre-GATT era and post-GATT era. In pre-GATT era, the term of patent was 17 years from date of grant of patent and in post-GATT era, the term of patent became 20 years from date of filing. William A. et.al also discussed about pre-AIA and post-AIA. Implementation of AIA changed filing system from first –to-invent to first-to-file and made provisional application filing necessary[11].

III. Objectives

To study patent law of India, China and US in field of pharmaceuticals

To compare patent law of India, China and US in field of pharmaceuticals

To draw inferences of patent law of India, China and US in field of pharmaceuticals

IV. Research Methodology

Data collection: Secondary data collection method adopted for collecting authentic data on - Patent Law in India, China and US

Secondary Data Collection: Through authentic websites of Government agencies of India, China and USA, Magazines, Scientific Journals, and News Bulletins.

V. Results And Discussion

Table 1 here

From Table 1, we have observed that novelty, non-obvious and utility are common criteria of patentability. There are few provisions which excludes some inventions from patentability. Compulsory licensing (CL) is a special provision under which patents can be granted without permission of patentee by paying royalty to patentee. CL is granted especially in case of pharmaceuticals.

Figure 1 here

Figure 1 mentions the revenue share of patented drugs, generic drugs and OTC medicines. In India, generic drugs are always preferred and share of patented drugs is very less. From this observation, it can be concluded that R&D spending and innovation is very less in India, so patented drugs makes only share of 9%

Figure 2 here

Figure 2 states that market of patented drugs has increased from 2008 to 2015, means innovative drugs have captured a good market in recent years but still India lags behind US and China in terms of new drugs.

Year 2016 marks an important year for some patented drugs as some blockbuster drugs are losing their patents and generic version will be effective which will make the drugs cheaper and easily available

The patentability criteria in India is novelty, inventive step, industrial applicability, in China it is novelty, inventiveness, practical use and in US, patentability includes novelty, non-obviousness and utility. In US, it is not compulsory that the invention must be having industrial applicability, if the invention is having utility, it can be patented.

Indian patent act 1970, did not give patent protection for pharmaceutical products to avoid monopoly of MNCs. But to comply WTO's TRIPS agreement, Indian started giving patent protection to pharmaceutical products for 20 years in patents (amendments) act 2005. On March 9, 2012 India's first CL was granted to Natco Pharma Ltd. to manufacture generic version Sorafenib of Bayer's corporation patented medicine Nexavar.

To protect the health of citizens, China's authorities did not give patent protection to avoid monopoly of pharmaceutical companies. So patent law 1984 excluded pharmaceuticals from patenting. But to enter WTO and to comply TRIPS, China revised its patent law and included pharmaceuticals and chemical products for patent protection. A product patent for a drug gives exclusive rights to patentee to manufacture, market, and sell the drug.

Patented pharmaceuticals in US depend highly on R&D and clinical trials on animals and humans, because to generate revenue, new drugs have to replace older drugs which are going off-patent. Pricing of patented drugs are set as per expenditure in R&D. Generic pharmaceuticals are cheaper version of drugs when their patents are expired. They contain same active ingredients, dosage strength, route of administration as of patented version. Generic version should meet USFDA regulatory requirements. These are biosimilars of patented drugs[22,23].

VI. Conclusion

The study conducted to compare patent laws pertaining to pharmaceuticals in India, China and US. CL plays an important role in field of pharmaceuticals. CL can be issued only after 3 years of grant of patent. In China CL can be issued within 3 years from the date patent is granted and within 4 years from filing date of patent. India has issue first CL for Nexavar but China has not issue any CL till date.

Acknowledgement

Authors acknowledge the immense help received from the scholars whose articles are cited and included in references of this manuscript.

Abbreviations

FY: Financial Year
CAGR: Compound Annual Growth Rate
USFDA: United States Food and Drug Administration
CL: Compulsory Licence
AIA: America's Invent Act
MNC: Multinational Companies
TRIPS: Trade related Intellectual Property Rights
WTO: World Trade Organisation
GATT: General Agreement on Trade and Tariffs

References

[1]. The Pharmaceutical Industry and the Patent System, http://users.wfu.edu/mcfallta/DIR0/pharma_patents.pdf, accessed on 20.7.16, time: 6:10

[2]. Pharmaceuticals, http://www.brandindiapharma.in/uploads/documents/Pharmaceutical-%20January%202016.pdf, accessed on 2.8.16, time: 6:01am

[3]. 2016 Top Markets Report Pharmaceuticals, http://trade.gov/topmarkets/pdf/Pharmaceuticals_China.pdf, accessed on 6.8.16, time: 11:46pm

[4]. Patents Against People: How Drug Companies Price Patients out of Survival, https://www.dissentmagazine.org/article/patents-against-people-how-drug-companies-price-patients-out-of-survival, accessed on 11.8.16, time: 11:29pm

[5]. The biotechnology drug revolution, https://www.optum.com/resources/library/bio-technology-drug-revolution-part1.html, accessed on 12.8.16, time: 12:36am

[6]. Pharmaceutical Research and Manufacturers of America, 2015 Biopharmaceutical Research Industry, http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf, accessed on 12.8.16, time: 12:38am

[7]. Wayne C. Jaeschke, Zhun Lu & Paul Crawford, Comparison of Chinese and U.S. Patent Reform Legislation: Which, if either, got it right?, The John Marshall Review of Intellectual Property Law, pp 566-600

[8]. William J. Bennett, Indian Pharmaceutical Patent Law and the Effects of Novartis Ag v. Union of India, http://openscholarship.wustl.edu/cgi/viewcontent.cgi?article=1500&context=law_globalstudies, accessed on 5.7.16, time: 6: 28pm

[9]. Geeta Anand, Inside India: India's Fight Against Big Pharma Patents Is a Just War, http://blogs.wsj.com/indiarealtime/2015/03/19/inside-india-indias-fight-against-big-pharma-patents-is-a-just-war/, accessed on 8.3.16, time: 4.59pm

[10]. Chen Changhui, Main amendments in draft of fourth amendments to the Chinese Patent Law, http://www.chinalawinsight.com/2015/05/articles/intellectual-property/main-amendments-in-draft-of-fourth-amendments-to-the-chinese-patent-law/, accessed on 26.2.16, time: 4:38pm

[11]. William A. Di Bianc, Brian R. Tomkins, GATT Patent Term? A Look Back at the Implementation and Ramifications of GATT, NYIPlA, Apr/May issue 2015, page no. 3-4

[12]. Draft Amendment OF The Patent Law Of The P.R.C. (Draft For Deliberation)

[13]. Chapter 2100 Patentability, http://www.uspto.gov/web/offices/pac/mpep/old/e8r9/mpep-2100.pdf, accessed on 21.7.16, time: 6:31pm

[14]. Compulsory Licensing. Chapter II: Government Use Under 28 USC 1498, http://www.cptech.org/ip/health/cl/us-1498.html, accessed on 18.7.16, time: 6:39am

[15]. Essential Medicines and Health Products Information Portal: A World Health Organization resource, http://apps.who.int/medicinedocs/en/d/Jh2963e/14.1.html, accessed on 26.7.16,time: 1:00pm

[16]. India way behind China in International Patents, https://factly.in/india-way-behind-china-in-international-patents/, accessed on 9.8.16, time: 12:10pm

[17]. Grounds for Compulsory Patent Licensing in United States, Canada, China, and India, http://cis-india.org/a2k/blogs/grounds-for-compulsory-patent-licensing-in-us-canada-china-and-india, accessed on 20.7.16, time: 6:53am

[18]. The Pharmaceutical Industry and the Patent System, http://users.wfu.edu/mcfallta/DIR0/pharma_patents.pdf, accessed on 20.7.16, time: 6:10

[19]. India defends right to issue drug 'compulsory licenses', http://www.reuters.com/article/us-india-patents-usa-idUSKCN0WP0T4, accessed on 1/8/16, time: 5:02pm.

[20]. The biotechnology drug revolution, https://www.optum.com/resources/library/bio-technology-drug-revolution-part1.html, accessed on 12.8.16, time: 12:36am

[21]. Pharmaceutical Research and Manufacturers of America, 2015 Biopharmaceutical Research Industry, http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf, accessed on 12.8.16, time: 12:38am

[22]. Pharmaceutical and Biotech Spotlight, The Pharmaceutical and Biotech Industries in the United States, https://www.selectusa.gov/pharmaceutical-and-biotech-industries-united-states, accessed on 12.8.16, time: 12:02pm

[23]. Pharmaceutical Research and Manufacturers of America (PhRMA) Special 301 submission 2016, http://www.phrma.org/sites/default/files/pdf/PhRMA_2016_Special_301_Submission.pdf, accessed on 12.8.16, time: 12:29

Tables

Table 1: Comparison of patent law in pharmaceuticals in India, China, US

S.No.	Patent Law	India	China	US
1	**Conditions of patentability**	**Chapter III of manual of patent practice and procedure, edition 2008:** For patentability, the drug must fulfill the criteria of novelty, must involve an inventive step and must be capable of industrial application	**Article 22 of Chapter II** states that inventions and utility models can be patented if they fulfill the criteria of novelty, inventiveness and practical use	Title **35 U.S.C. 101** states that invention should be novel, non-obvious, utility
2	**Inventions not patentable**	As per Chapter II of Indian Patent Act, **section 3(d) and section 4** describes non-patentable inventions.	**Article 5 and 25 of Chapter II** mentions exceptions in granting Patent rights	**Chapter 2100** states non-patentable subject matter
3	**Types of patents**	[12]In Indian perspective three types of patents can be granted: **Ordinary patent** **Patent of addition** If a patent application is filed by applicant, then **convention application** must	**Article 2 of Chapter I** mentions types of patents: **Invention patents** **Utility models or utility patents** **Designs means overall product or its parts**	**USC title 35** describes types of patents: **Utility Patents** **Design Patent** **Plant Patents**

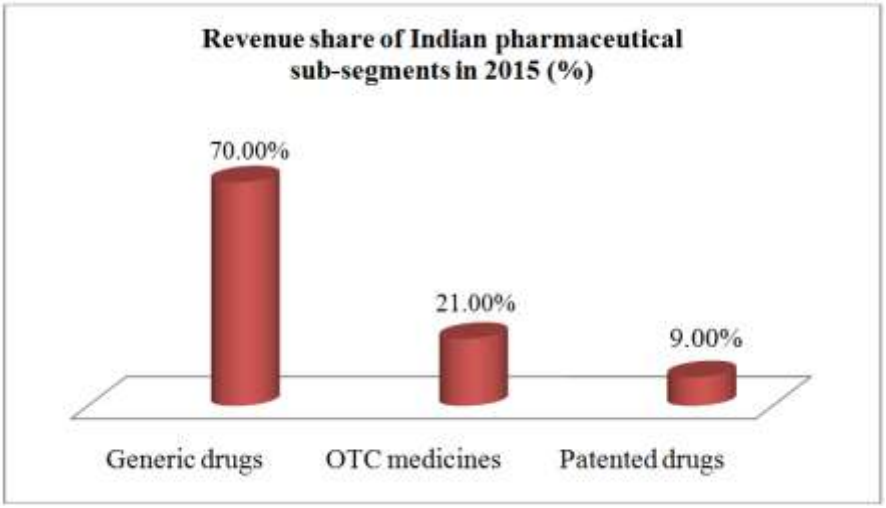
		be filed within one year from date of first application in one or more convention countries.		
4	**CL for pharmaceuticals**	U/S 92A: CL can be issued by Controller to the applicant for manufacture and export of patented pharmaceutical product to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems.	Under article 50, for the benefit of public health, patent administration department under the State Council may grant a compulsory license to manufacture and export of patented drugs for exploitation of an invention patent or utility model patent.	US patent law does not give provision for CL in pharmaceuticals

Table 2: The drugs losing patents in US in 2016

Brand name	**Gleevec**	**Crestor**	**Seroquel XR**	**Benicar**	**Zetia**
Generic name	Imatinib Mesylate	Rosuvastatin Calcium	Quetiapine Fumarate - Extended Release	Olmesartan	Ezetimibe
Manufacturer	Novartis	AstraZeneca	AstraZeneca	Daiichi Sankyo	Merck
Treatment	Cancer	High cholesterol	Schizophrenia	Blood pressure	Lower LDL cholesterol
Year of FDA approval	May 10, 2001 (Capsule) April 18, 2003 (Tablet)	August 2003	May, 2007	June, 2003	Oct 2002
US Patent expiry	Feb 2016	May 2016	Nov 2016	Oct 2016	Dec 2016
Price of patented drug	$120,000/year	$39/30 tablets-$83.88/30 tablets	$264.76/30 tablets-$800.16/30 tablets	$181.80/30 tablets-$231.90/30 tablets	$156.47/30 tablets-$352.75/30 tablets
Price of Generic drug	$60,000/year	$32/30 tablets-$47.7/30 tablets	App. $200	$40.95/30 tablets-$102.51/30 tablets	App. $53/30 tablets
Generic version launch by company	Sun Pharma	Mylan Pharmaceuticals	Mylan Pharmaceutical, Osmotica Pharmaceutical and Torrent Pharmaceuticals are in competition to launch generic drug	Mylan Pharmaceuticals	Glenmark
Revenue	$4.65bn(2015) $2.53bn(2016)	$5.02bn (2015) $6.62bn (2011)	$1.03bn (2015) $5.8bn (2011)	$2.44(2012) $2.60(2011)	$2.53bn(2015) $2.8bn(2013)

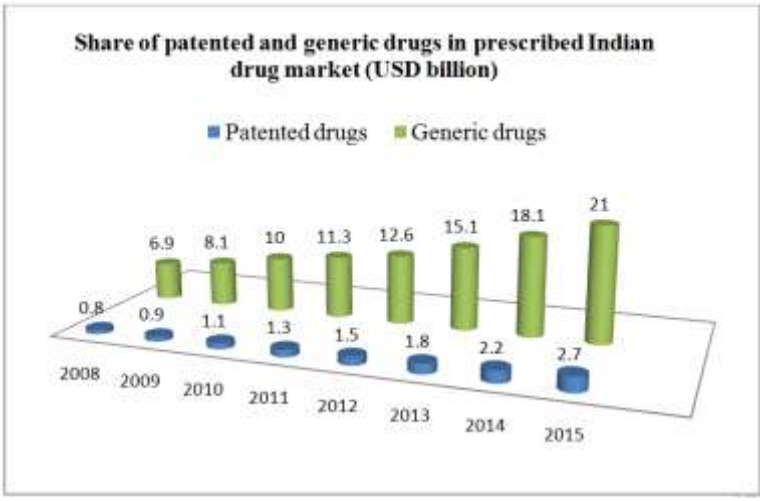
Source: Compiled by author

Figures



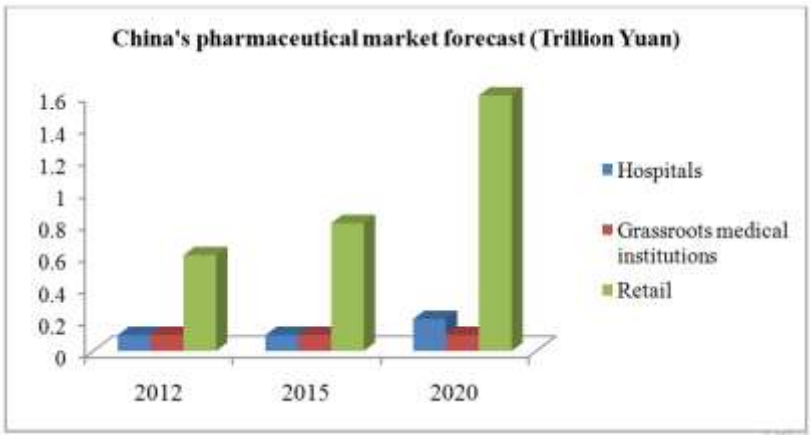
Source: Business Monitor International, FCCI Indian Pharma Summit 2014-15, TechSci Research

Figure 1: Revenue share of Indian pharmaceutical sub-segments in 2015(%)



Source: BMI, TechSci Research

Figure 2: Share of patented and generic drugs in prescribed Indian drug market (USD billion)



Sources: CPA, McKinsey

Figure 3: China's pharmaceutical market forecast (Trillion Yuan)

IOSR Journal of Pharmacy and Biological Sciences (IOSR-JPBS) is UGC approved Journal with Sl. No. 5012, Journal no. 49063.

Pise Shilpa A. "To Study and Compare Patent Law Pertaining To Pharmaceuticals in India, China and US." IOSR Journal of Pharmacy and Biological Sciences (IOSR-JPBS), vol. 12, no. 5, 2017, pp. 01–06.