

Strategic Analysis of Intellectual Property Rights Practices in Pharmaceuticals from India, China, and US

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ABSTRACT

Aim: The study was conducted to compare the attitude of IPR (Intellectual Property Rights) experts about patent law in pharmaceuticals from India, China and US

Research methodology: This is a questionnaire based study to know the opinion of IPR experts from India, China and US. The purpose of this research is to know about patenting in Pharmaceuticals in India, China and US. Various factors were analysed about patenting in field of Pharmaceuticals.

Results and discussion: The answers of questionnaire were received by respondents and responses were analysed based on their answers. Various factors were analysed like impact of technology improvement, safety, efficacy, use, evergreening on pharmaceutical patenting.

Conclusion: Responses were highly appreciated to proceed the study and we came to know about different aspects of pharmaceutical patenting.

Keywords: Pharmaceuticals, patentability aspects, patentability criteria, patent law

INTRODUCTION

Patenting a pharmaceutical is bit time consuming and different than other technology fields. For an invention to be patentable, it must fulfill the criteria of novelty means that invention should be new and it should not be available in public domain prior to filing of application. Novelty assesses the uniqueness of invention. Inventive step means that invention should be non-obvious and should be an advancement in existing technology. Industrial application means that invention can be used commercially and on large scale so that maximum number of people can take benefits. The basic fact of these criteria remains the same with some modifications in India, China and US. US follow the criteria of novelty, non-obviousness and utility.

Patents vary from industry to industry and also they work differently in different industries. In field of technology, the patent can be used by licensing among competitors and also it is not much difficult to get patents in field of technology as compared to pharmaceuticals. In field of pharmaceuticals, it is not easy to obtain a patent as pharmaceutical patents are generally product patents. A lot of time and money is spent in R&D and clinical testing process to launch a pharmaceutical drug in market. In field of pharmaceutical and chemical industry, it is easy to duplicate the process. ^[1]

The first amendment to Indian Patent Act was made in 1999 which facilitated the 'Mail Box' system and the Exclusive Marketing Rights for product patented. From January 1, 1995, the process

of accepting the patent applications under mailbox was initiated, which will be processed in 2005.

Patent history of China is not old. Patent Law of the People's Republic of China came into force on 1 April 1985. It was amended three times in 1993, 2001 and 2009. The third amendment became effective as of 1 October 2009. There are three types of patents in China: invention patent, utility model patent and design patent and period of patent protection is 20 years for invention patents, 10 years for utility model patents and 10 years for design patents. The important goal of patent law is to encourage scientific research, new technology and industrial progress. It provide exclusive right to own, use or sell the method or the product patented for the limited period, stimulates new inventions of commercial utility. The Chinese Patent Office of the State Intellectual Property Office (SIPO) provides monopoly to the inventor for invention after inventor discloses the invention to patent office for limited period of 20 years, 10 years and years for invention patent, utility model patent and design patent respectively. After the expiry of the fixed period the monopoly passes into public domain.^[2]

The United States is the world's largest pharmaceuticals market and US's biopharmaceutical industry is the world leader in medical research. As per report of Pharmaceutical Research and Manufacturers Association (PhRMA), U.S. pharmaceutical firms conduct the majority of the world's research and development and are involved in inventing, manufacturing, marketing of most new medicines. The industry work in collaboration with universities, clinical researchers, patient organizations, healthcare providers. As per one report, 7000 new medicines are in pipeline or development stage worldwide and out of this approximately half i.e. 3500 compounds are being studied in US. New patented technologies in pharmaceuticals have improved the life expectancy and decreased burden of diseases.

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.^[3,4]

RESEARCH METHODOLOGY

A set of five questionnaires was sent to IPR experts to know their opinions about patentability aspects, patentability criteria, influence of patentability, influence of patent amendments on pharmaceuticals in these countries

Primary data collection: primary data was collected from IPR experts via e-mail or telephonic communication. A questionnaire was created and distributed to respondents via e-mail. The information obtained from secondary sources helped in processing of primary data

Secondary data: secondary data about IPR aspects in pharmaceuticals was collected from news articles, published research papers, magazines, journals, newspaper (used mainly for India), official websites of mentioned countries. As this is a conceptual study, so secondary data is also an important source to collect the exact information from official websites of respective countries as many respondents did not answer the all questions and they have directed to follow the official website of their respective countries and they have provided links about their published articles in various journals.

Inclusion Criteria: IPR experts mainly from field of pharmaceuticals were included in the study to make the study more specific and to know exact answers of questions. Though information about hundreds IPR experts was available but we were specific

about pharmaceuticals so that exact and authentic information can be obtained.

RESULTS

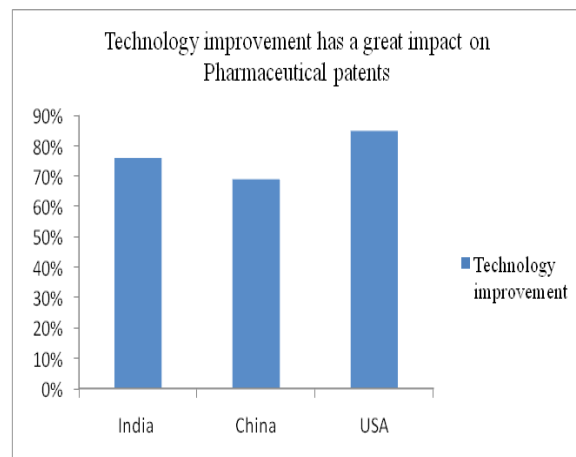
The questionnaires were sent to 200 IPR experts of India, China and US. Out of this, we got response of 30 respondents. The questionnaires were sent via e-mail to all the respondents. Telephonic communication was also done with many respondents but response via telephonic communication was nil from China and US. The response rate via telephonic communication was good from India but not much successful, so information received via e-mail was processed as e-mail communication was found more effective than telephonic communication because respondents could not spare much time via telephonic communication. They responded via e-mail as per their suitability.

The answers of questionnaire were received by respondents and responses were analysed based on their answers.

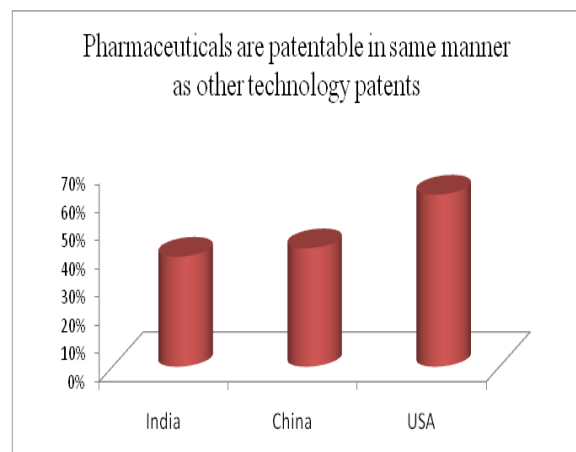
DISCUSSION

Various aspects were analysed from responses of IPR experts. Technology improvement has great impact on pharmaceutical patents. The responses of IPR experts which can be clearly estimated from graph (1), 76% responses from India, 69% responses from China and 85% responses from USA says that technology has a great impact on patenting. Graph 2 mentions about patenting of pharmaceuticals in same as other technology field patents, 39% from India, 42% respondents from China and 61% respondents from US give their opinion about pharmaceuticals are patentable in same manner as other patents. In India, rules of patenting a medicine are stringent and respondents from India with response rate 78% have confirmed the statement followed by China 66% and USA 48% (graph 3). Evergreening a patent, this concept is mainly used in USA where patents can be granted with some modifications and improvements, as this allows monopoly to patentee to manufacture, sale, market the

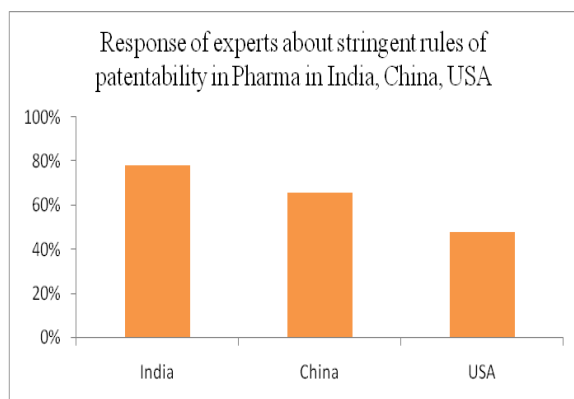
drug. But in countries like India and China, where population is huge and many people die because of shortage of medicines or inadequate supply or due to high cost of medicines, concept of evergreening and improvement in existing drug is not feasible. Immediately, the drug goes off-patent, generic version is launched so the need can be fulfilled. The response rate from respondents for evergreening and improvement in India (43%), China (62%), USA (78%) as evidenced from graph 4. USA grant maximum no. of patents in Pharma and response rate of IPR experts is also in favor of USA (85%), China (65%), India (42%). Spending in pharmaceutical R&D is maximum in USA. In spite of technological improvement, safety and efficacy plays very crucial role of drug patenting, respondents rated this in India (89%), China (82%), USA (92%) (graph 6)



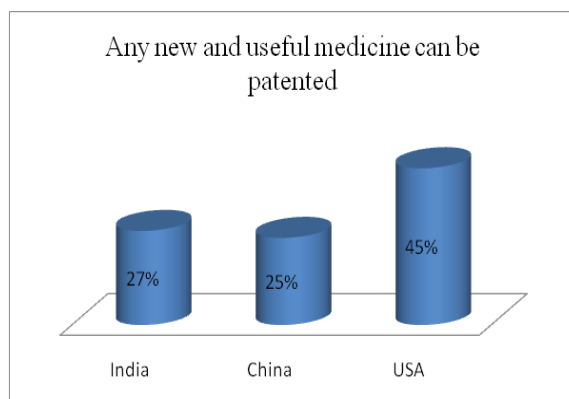
Graph 1: Technology improvement has a great impact on Pharmaceutical patents



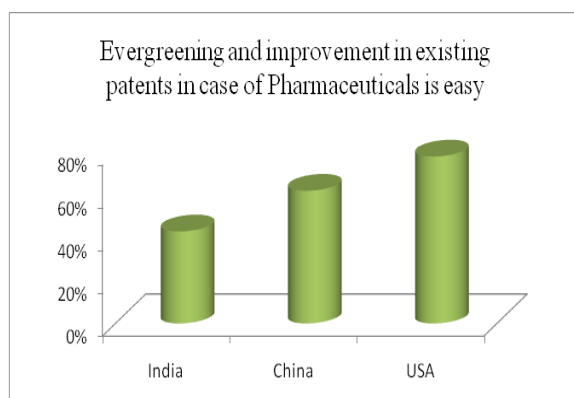
Graph 2: Pharmaceuticals are patentable in same manner as other technology patents



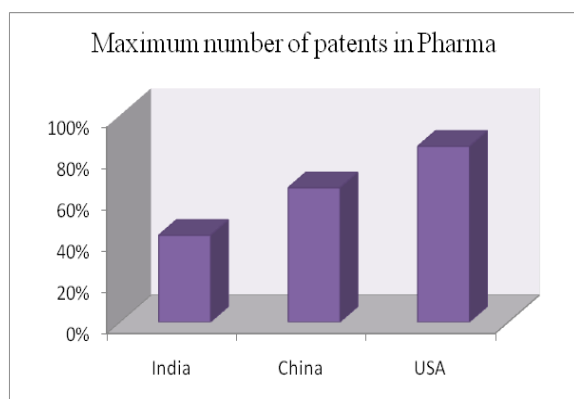
Graph 3: Response of experts about stringent rules of patentability in Pharma in India, China, USA



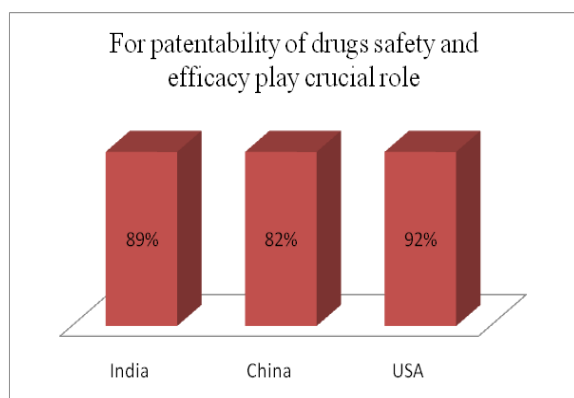
Graph 7: Any new and useful medicine can be patented



Graph 4: Evergreening and improvement in existing patents in case of Pharmaceuticals is easy



Graph 5: Maximum number of patents in Pharma



Graph 6: For patentability of drugs safety and efficacy play crucial role

CONCLUSION

From the above study, it can be concluded that responses were highly appreciated to proceed the study and we came to know about different aspects. Though complete information is available on internet about everything but experiences of IPR experts helped in easy compilation. Improvement in technology, safety, efficacy, and usefulness of drug helps in patenting the drugs, but also these factors vary from country to country because as per their patent laws, preferences are given to each factor. India is lagging behind in various aspects followed by China. USA uses advanced technologies so has maximum no. of patents and also USA not follow much stringent rules in patenting which make it the world leader of patents not only in field of Pharmaceuticals but in every technological field.

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