Impact of Patents on Indian Pharma Industry’s Growth and Competency: A Viewpoint of Pharmaceutical Companies in India

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Instruments of intellectual property rights (IPR) are considered to achieve economic, social and technological advancement for a country in all aspects. Of all the instruments of IPR, patent is the most contentious issue which is deliberated in several international fora. Patents are mostly debated for their role in pharmaceutical field. India signed General Agreement on Tariffs and Trade (GATT) in 1994 agreeing to implement the IPR in all fields of technology, including product patent, with effect from 1 January 1995. Taking into account India’s status as a developing country, India was granted a transition period of ten years from 1995 to 2005 to switch over from process patent to product patent. With this shift, it was imperative for Indian pharmaceutical companies to embrace product patents. This study was undertaken with the objective of identifying the situation in India after product patent regime was implemented. The role of Indian pharmaceutical companies in the era of product patent is crucial. The authors attempted to identify how Indian pharmaceutical companies view product patent regime, hindering the growth of industry or providing impetus to R&D, in this study. The measures taken by these companies to survive and grow in product patent regime have also been analysed.

Keywords: Pharmaceutical industry, TRIPS, product patent, R&D, IPR department

India’s accession to World Trade Organization (WTO) and obligation to implement Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement has seen the change in Indian pharmaceutical industry. The industry had to adopt product patent in all fields of technology from 2005, which was restricted to process patent and a term of 5-7 years under Indian Patents Act, 1970. The generic pharmaceutical industry in India that thrived on process patent and ‘reverse engineering’ was no longer allowed to do so. On one hand, the implementation of TRIPS put restrictions on Indian pharmaceutical industry in terms of producing generic drugs; on the other hand, it opened up opportunities for the industry in terms of investment in Research and Development (R&D) of new molecules. Many Indian pharmaceutical companies viewed patent system with a positive attitude and started gearing up for the same. A few of them viewed it as an opportunity and earmarked budgets for basic R&D. It is in the recent years that Indian companies started charting their growth path. Some big companies on the one hand are involved in the basic research while on the other hand they manufacture generic versions of ‘off patent’ molecules. It would be interesting to see how Indian pharmaceutical companies sustain their momentum of growth and develop new competencies to overcome the challenges posed by product patents regime.

Objective of the Study
The basic objective behind this study was to analyse the product patent implications and its impact on Indian pharmaceutical industry in terms of growth and competencies in India in post-TRIPS era.

Research Methodology

Research Design
A good research design ensures that research project is conducted effectively and efficiently.1 The research design used in this work is an exploratory research as qualitative analysis derived from the study.

Data Source
Data sources are an important tool to identify the source of information. Secondary data for this study was collected from available literature. However, the primary data was collected with the help of a well framed questionnaire. Primary data was also collected from experts in the field of intellectual property by having discussions with them.

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Types of Data
The types of data used in this study were based on categorical variables, such as, ordinal and nominal.

Data Collection
The relevant data was collected by sending questionnaire to the selected sample unit within the population. Since non-personal form of data collection method is used, the researcher and the respondent did not come in contact with each other, eliminating any bias.

Questionnaire Design
The objective of using a questionnaire was to access decision makers in various pharmaceutical companies selected on the basis of different geographical locations in India.

Type of Questionnaire
The questionnaire framed for this study was disguised in order to reduce respondent bias. The questionnaire included dichotomous, multiple choice questions along with open and close ended questions.

Sampling Design
Sample Frame
As this study did not involve probability sampling, sampling frame was not required.

Sample Unit
Sampling unit included managers working in pharmaceutical industry in intellectual property management department.

Sampling Method
Since, this is an exploratory study; the sampling method used was non-probability convenience sampling.

Sample Size
The method used to decide the sample size was an unaided judgment. The questionnaire was mailed and communicated to the probable respondents in the pharmaceutical industry. The samples selected were from top 25 companies listed by ORG MARG and who are actively pursuing the path of R&D in India. Out of 25 respondents, 10 respondents denied to answer citing confidentiality reasons. So, the sample size for this study included 15 respondents.

Analysis and Interpretation of Data
Data collected from questionnaire were tabulated. The tabulation included deducing information from open ended, multiple choice and dichotomous questions. The responses to open ended, close ended and dichotomous questions were coded in order to analyse the responses objectively. The responses were analysed in the context of problem at hand.

Results and Discussion
The study included the responses from big-, medium- and small-scale companies in India. This study did not include any response from MNCs as comparison with MNC could lead to a bias in analysis.

Existence of IPR Department in the Company
The first question posed to respondents was whether their company has an IPR department or IPR division. All the respondents answered in affirmative. Not a single company had said that they do not have an IPR cell. This shows the commitment on the part of Indian pharmaceutical companies to adhere to TRIPS requirements. This does not mean that all the companies have devoted their resources for basic R&D. Respondents were further asked the number of years since the patent cell was established in these companies. It was surprising to see that out of 15 responses only one response stated that IPR cell was established in the year 1995, the year from which India was given transition period of ten years. The majority of the companies started IPR cell after 2000. By the end of year 2004, the majority of companies started a separate department to look after the issues related to patents. The reason for asking the year of establishment was to understand where these companies stand in terms of understanding issues of patent in a short span of time. It can be safely presumed that the patents that are granted to Indian pharma companies or applied by these companies are for either new processes or new drug delivery systems. Additionally, information provided by Ranbaxy to Mashelkar Committee suggests that patents have been obtained in the US, primarily, for generics.

Industry Institute Collaboration
Regarding collaboration with academic institutes for developing and patenting a technology, roughly half of the companies (eight out of a total fifteen responses) responded in negative. This question was specifically asked as the intensity of industry academia interaction is dismal in India. The multinational companies in western countries
collaborate with academic institutes in order to focus on research. Only a few Indian pharmaceutical companies (seven out of a total fifteen responses) have collaborated with academic institutes for carrying out basic research. Companies having collaboration with more number of academic institutions imply that these companies have diversified their research interest. Companies that responded in negative for collaborative research were further asked whether they would be interested to collaborate with academic institutes. Half of them responded in negative (four out of a total eight responses). Three companies responded in affirmative that they were interested in having collaboration with academic institutes but did not provide the time frame for collaboration.

Impact on Pharmaceutical Industry after Product Patent Regime

The next question was with respect to product patent regime and growth of pharmaceutical industry. The companies were asked whether the product patent regime would impede the growth of Indian pharmaceutical industry. Companies are optimistic as there would be alternatives available to them to market generic version of medicines that are going off patent in near future (2008-2012). Ten companies responded that the product patent will not impede the growth of Indian pharmaceutical industry. However, three companies showed concern that the product patent regime would be detrimental for the growth of the industry.

The companies that opined that product patent regime would be detrimental were further probed as to what factors they consider would impede the growth of the industry. The first factor cited was competition from MNC’s. With product patent in place ‘reverse engineering’ would no longer be the case as Indian generic manufacturers will compete with multinational companies. Another factor was chances of increase in patent litigation cases. However, monopoly; price rise of medicines; and survival of small- and medium-scale companies were other factors which will have direct impact of product patent in force, as observed by the members of the companies. As generics business formed the backbone of Indian industry, transformation to product patent regime does not seem smooth. Many roadblocks exist in transformation from process to product patent. Some respondents stated that with implementation of product patent, with an apprehension that the situation would revert back to that existed before 1970, when MNC pharmaceutical companies had more than 75% of market share. Concerns regarding imbalance in market and setback for Indian companies were also expressed by the respondents. The optimistic responses in relation to growth of Indian pharma industry in product patent regime were overwhelming. The respondents cited that with implementation of product patents in India, more resources would be devoted to basic research. The industry does not have resources to commercialize the products. One of the options suggested was licensing of molecules during different stages of development. Indian pharmaceutical industry would become a part of global research industry and a lot of work would be outsourced to India. The respondents also expressed that India would emerge as an intellectual hub protected by national IP laws. A highly optimistic response stated that Indian industry would be able to produce around 2-3 NCE (New Chemical Entities) by the end of 2015.

Overall people expressed the view that Indian pharmaceutical industry will continue on its growth trajectory without having to worry about product patent. Many other opportunities exist for the industry where companies can take advantage without violating the IP laws.

Survival and Growth of Indian Pharmaceutical Industry

Respondents were asked what they feel regarding the chances of survival and growth of the industry in product patent regime, and to rate their opinion on a five point scale where five means strongly agree and one mean strongly disagree. Except one respondent, all agreed that the industry would not only withstand the pressure imposed by product patent in terms of survival but would have fair chances of growth. Moreover, the survival and growth of companies would be governed by maneuvering with the business strategy to withstand competition from multinational pharmaceutical companies.

Next question was to explore the reasons for not establishing a patent cell or IPR cell by the companies. Four options were given to the respondents; ‘lack of infrastructure’, ‘procedural difficulties’, ‘financial incapability’; and ‘did not feel the need to have an IPR cell’. The majority of respondents stated that the major reason for not establishing an IPR cell by many companies was due to lack of infrastructure. Lack of infrastructure within a company is related to knowledge regarding the
The use of resources to acquire patents, filing of patents, insufficient or non-qualified staff, and lack of competent people that can be entrusted with the activities of acquiring, defending, and challenging patents. Respondents also stated that Indian companies did not feel the need to have a patent or IPR cell because some of the companies hired the services of consultants such as a patent attorney or a patent agent. Financial incapability was considered as one of the barriers for the establishment of a patent cell. These responses were given by people working in small- and medium-sized enterprises. Financial incapability not only relates to filing and acquiring patent, it also implies that finances are to be reserved in case a litigation or dispute arose with the competitor. It is not surprising to see that lack of infrastructure was cited as one of the major reasons for not taking initiative with respect to establishment of a patent cell.

Indian Scientific Community

A question was asked with respect to the respondents' view on the strength of Indian scientific community and their capability to get patents. Out of total 15 responses, 12 respondents stated that they rate Indian scientific brilliance to be good or excellent in terms of developing and patenting a technology. It is again reiterated by the fact that Indian scientists are renowned globally for their technical and scientific prowess.

Lucrative Market for Filing Patents

The respondents were asked whether they consider US, EU, Japanese or Indian patent to be more beneficial. The majority of respondents consider that the US market provides them with more and better opportunity followed by European market. Japanese market and Indian market were not considered to be lucrative for filing a patent. According to IMS data, sales through retail pharmacy have increased by 3% in North America which is estimated to be US$ 224.6 billions, out of which the US accounts for US$ 207.4 billions. In Europe the sales through retail pharmacies have gone up by 3% and are estimated at US$ 116.8 billions. Thus, it is not surprising when respondents believe filing patents in US and EU is advantageous in terms of business opportunities. It is evident from the data that many Indian pharma companies have increased patent filing in US in recent years.

Use of Patent Cooperation Treaty to File Patents

Patent Cooperation Treaty (PCT) basically aims at simplifying procedure to file in multiple countries simultaneously without losing rights to priority date. The respondents were asked whether PCT would be beneficial for filing patent applications for companies in developing countries. It is important to note that PCT does not grant or reject a patent application. It merely facilitates or provides a mechanism through which a company can file for patent application in several countries. All the respondents agreed that PCT will be beneficial to companies in developing countries as it tries to reduce bottlenecks with multiple filing, save time and money for the companies. It also provides 30 months time to applicant to decide the countries in which an application for patent to be filed without losing priority to an invention.

Limitations of the Study

The following limitations had been observed while conducting the present study:

(i) The sample size is very small and is just an indicative of opinion of people working in pharmaceutical industry. Since, the perception with respect to IP is subjective, the opinion of the respondents should not be generalised as opinion of the entire Indian pharmaceutical industry.

(ii) The responses from some companies could not be collected as managers in these companies cited confidentiality reasons and company policy of not revealing such confidential information.

(iii) This is an indicative study to assess impact of Patents (Amended) Act, 2005 and should not be construed as a conclusive study with impact of product patents on Indian pharmaceutical sector.

(iv) The responses are not segregated on the basis of large-, small- or medium-scale enterprises.

Conclusion

It is observed that the people working in IP Management Department of various pharmaceutical companies are confident that India would be a big player in pharmaceutical sector in coming years. They are confident that Indian scientists have capabilities to develop and protect intellectual property. The companies that responded have all been late entrants in the field of IPR. Nonetheless, these companies have attained remarkable progress. Increased awareness regarding patents has helped companies file patents in lucrative markets. International treaties like PCT could
be helpful to Indian companies with respect to filing multiple applications.

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