To Study The Scope & Importance Of Amended Patent Act On Indian Pharmaceutical Company With Respect To Innovation

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Abstract

The Indian pharmaceutical company has been built from an industry that copies patent drugs and manufactures them inexpensively. Now it is counted amongst the industries that are fuelling India’s economic growth and holds enormous potential. Indian-based pharmaceutical companies are also predicted to gain considerable market share in the world. It ranks third world wide, in terms of technology, quality and range of medicines manufactured. Indian Pharma Company fulfils around 70 percent of the country’s demand all together. Currently, it’s estimated to be worth US$4.5 billion, and is growing at nearly 8 to 9 % annually. Due to amended patent act there are an assortment of changes took place in Indian pharma industry. The primary objective of this paper is to study significance of the amended patent act on pharma industry. The paper also allows study of the scope of amended patent act.

Keywords: Amendment, innovation, IPR, Pharma companies

1. Introduction

Pharmaceutical industry in pre-TRIPS period: The Pharmaceutical Industry witnessed a change after the formation
of World Trade Organization (WTO) in 1995 when India, being a signatory member of WTO, adopted Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. Indian pharmaceutical company is about 120 years old. Production of modern medicine by indigenous units started with the setting up of Bengal Chemical and Pharmaceutical works in Calcutta (1892), which was followed by the establishment of Alembic Chemical works in Baroda (1907) & Bengal Immunity in 1919.

At that point of time, the Patents Act of 1911 was in practice, which facilitated patenting all the known and possible processes of manufacturing a drug besides patenting the drug itself. Foreign multinational corporations (MNCs) were quick to take advantage of this provision. They consistently imported bulk drugs from their home countries & produced/mixed formulations in India, contending that locally available bulk drugs were not of desired quality. They also patented heavily in the country. The indigenous firms were legally prevented from manufacturing most of the new drugs introduced by the transnational corporations (TNCs) during the life of the patent secured by the latter, i.e., for 16 years, which could be extended to a maximum of another 10 years if the working of the patent had not been sufficiently remunerative to the patentee. The domestic firms were also forbidden from processing a patented drug into formulations or importing it. As a result, at the time of independence, the industry was dominated by multinational corporations and the prevailing drug prices were among the highest in the world. Between 1947 & 1957, ninety-nine percent of the 1704 drugs & pharmaceutical patents in India were held by foreign multinational enterprises which controlled 80 percent of the market. To study patents & provide suggestions on the type of patent system that India should implement, two expert committees were established in independent India. The Patent Enquiry Committee (1948-50) reported that, “the Indian patent system has failed in its main purpose, namely to stimulate inventions among Indians and to encourage the development and exploitation of new inventions for industrial purposes in the country so as to secure the benefits thereof to the largest section of the public.”

The second committee, known as the Ayyangar Committee (1957-59), noted that foreign patentees were acquiring patents not “in the interests of the economy of the country granting the patent or with a view to manufacture there, but with the object of protecting an export market from competition from rival manufacturers particularly those in other parts of the world”. Thus India “is deprived of getting, in many cases, goods at cheaper prices from alternative sources because of the patent protection granted in India”. These reports concluded that foreigners held 80-90 percent of the patents in India and were exploiting the system to achieve monopolistic control of the market.

The committees therefore suggested that a patent system, which focused on access to resources at lower prices, would be beneficial to India. The Patent Act of 1970 was based on the recommendations of these committees. The act found support among domestic firms and various political parties in India. Under this act, only one process that was used in the actual manufacturing could be patented. The period 1970-95, generally known as pre-TRIPS period, was a flourishing phase of Indian pharmaceutical company.
However, the scenario again changed when the world trade organization (WTO), was established in 1995 as a successor to the general agreement on tariffs and trade 1947 (GATT-1947). India was a founder member of the GATT-1947 and the WTO-1995. Being a signatory member of WTO, India had signed onto TRIPS. Under TRIPS, all countries have to provide for protection of product patents from Jan 1, 1995. However, developing countries like India, which did not have a regime of product patents, could avail a transition period of ten years - until January 1, 2005 Domestically and internationally India resisted conforming to TRIPS and refused to comply with its provisions earlier. The simple reason was that to conform to TRIPS, India would have to revise one of the main aspects of its patent policy that only process and not product patents would be granted to pharmaceuticals and agrochemicals. However, perspectives about IPRs in India changed over time and caused a marked shift in India’s policy around 1998-99. Industry bodies and various groups changed their stand and now took a pro-patent view. The CII (Confederation of Indian industry), ASSOCHAM (Associated chambers of commerce and industry of India), and even FICCI, the most influential representative of Indian industry, now started favoring intellectual property rights. Even some domestic firms like Dr. Reddy’s laboratories and Ranbaxy who had been prospered under the existing patent structure, now started visualizing significant avenues for profit from the new patent regime. As a result, a marked shift in India’s policy occurred around 1998-99. Accordingly ‘The Patent Act 1970’ was amended. Three amendments viz. The Patents (Amendment) Act, 1999, The Patents (Amendment) Act, 2002 and The Patents (Amendment) Act, 2005, were made to the patent Act 1970 with a view to fulfilling India’s obligation of the TRIPS requirements.

2. Pharmaceutical industry in post-TRIPS period (after 1995)

The period 1995-2008 (i.e. the post-TRIPS period) saw the strongest performance of the Indian pharmaceutical company on several fronts. TRIPS compliance of the intellectual property right regime has not reduced the innovation capacity of the domestic pharmaceutical industry which has visualized an increase in both, research budget and patenting. The recent surge in patent applications in India in the post-1995 period, has now received attention in policy analysis. It provides important data for evaluating the potential for domestic actors to adjust to the new patent regime. The number of patent applications filed in the Indian Patent Office has risen approximately 420 per cent in 2006 from 1995. In terms of the number of PCT international applications (IAs) filed in 2008, India stood at 18th position. R&D expenditure as a percentage of sales, which stood at around 2 percent in 1993-94, increased to around 5 percent in 2005-06. Presently, Indian pharma companies are increasing the number of regulatory filings such as DMFs and ANDAs as these enable them to manufacture and market drugs in the regulated markets such as the United States and Europe.
3. Research Problem and Questions

1) What is the significance of IPR in Indian pharma industry?
2) How amended patent act is changing the scope of Indian pharma industry?
3) What is the effect of amended patent act on Indian pharmaceutical product?

4. Importance of the Study

In order to be evidence for the Indian Pharma companies in a path that have huge benefits by amended Patent act on the marketing activity in the way that best fit the consumers. This study will be useful for providing importance and scope of IPR for the Indian pharma companies for patenting the molecule.

5. Hypothesis

1. Indian 2005 amended patent act resulted in pharmaceutical companies to motivate for innovation. Clustering: Patented product introduced Companies R and D expenditure &Companies Turnover.
2. Implication of amended patent act has resulted in improving Economic status of Indian pharmaceutical companies. Clustering: Number of patented product introduced, Turnover.

6. Research Limitations

a) The study was restricted to pharmaceutical industry located around Mumbai and Pune region, lawyers and doctors located in Pune.
b) The study focused on pharmaceutical industry and Amended patent act 2005 only and hence results of the analysis are not applicable to any other type of industry.

7. Literature Review

The article by Dr. A. Selvaraj focuses on compatibility of Indian pharmaceutical company. Production wise, Indian manufactured drugs are at quite economic rate. The reasons are like infrastructure cost, labor cost, clinical trial cost, etc. but India is lacking in patented drug manufacturing. As compare to western countries, R & D activities of pharmaceutical industries are not up to the expectation. This can be because of process patent agreement. As per the editorials Ravi Kiran, SunitaMistra which focus on the changed scenario due to Amended Patent act 2005, India as a signatory member signed TRIPs for protecting product patent, preliminary India refused for the change. This can be because of n number of reasons like if product patent becomes compulsory licensing may get affected, price of medicine may increase etc. patented product is like an asset to the company. It increases profitability of respective company and future competition or turnover won’t be on sale of product but it will beon the number of patent a company is holding. Indian domestic as well as international company understood the need of research activity to survive in market and nowadays most of them are changing from imitation to innovation by increasing R and D
activity to sustain in market. The article by R Saha talks about the innovation and need of innovation. India has signed TRIPS agreement in which the protection of intellectual property rights are obligatory in chemical, food and drug industry. Consequently to accept the changed scenario, not only Indian pharmaceutical companies but also government needs to adopt new strategies or policies to increase or motivate research and development activities in India. In amended patent act 2005, government has come up with different policies like tax exemption, funding, collaboration with academic, public and private sector etc to increase research and development activities. Indian pharmaceutical companies have adopted new strategies like collaboration, merger and acquisition, outsourcing etc to increase research and development activities.

8. Research methodology

Research design: Descriptive research design.
Population: Indian pharmaceutical company, lawyers and doctors
Sampling Area: Mumbai and Pune region

The term Mumbai and Pune Region used in this study refers to area carved out by the pharmaceutical industry for its high rate of development. Mumbai and Pune region as understood in the Pharmaceutical Marketing phraseology is quite a large area spread over. There are around 300 pharmaceutical companies which are catering to the population of this area. Hence it was possible only to obtain data from the representatively selected top 25 pharma companies based on purposive sampling, in Mumbai and Pune region, having major market share. Doctors with different specialization like radiologist, gynecologist, cardiologist etc& practicing since 8 years are considered from Pune city. Patent experts practicing in private firms are contacted to collect information, whose experience is more than 10 years in Pune city.

Sampling Technique: Non-probability purposive sampling for pharmaceutical companies, stratified convenience sampling for lawyers and doctors
Sample Size: Total -60
Doctors – 30 with different specializations
Patent Experts – 5 practicing in private firms
R and D, Legal department etc of Indian pharmaceutical company – 25

Research Instrument: Personal Interview, structured Questionnaire
Tool: With a view to obtain data from the field, three different questionnaires designed , one for the pharma companies managers, second for patent experts & the other for doctors, have been prepared & administered. The responses received have been tabulated & statistically analyzed.

E sources: Internet, sites, journals, publications, articles, online research papers etc.

Data Analysis procedure: The field survey and personal interview technique adopted for data collection and
collected data has been tabulated and presented with the help of graphs, tables and charts. Both descriptive and inferential statistics were used in presenting and analyzing the data. Descriptive tools such as frequency counts, mean scores, percentages were calculated for the statements on the questionnaire in order to determine the impact and its related issues.

Statistical Technique: Chi-square is a statistical test commonly used to compare observed data with expected data to obtain according to a specific hypothesis. The test allows research student to compare a collection of categorical data with some theoretical expected distribution.

9. Data analysis

1. Indian 2005 amended patent act resulted in pharmaceutical companies to motivate for innovation.

   **H0**: Indian 2005 amended patent act has not motivated pharmaceutical companies to motivate for innovation.

   **H1**: Indian 2005 amended patent act motivated pharmaceutical companies to motivate for innovation.

   **CALCULATION:**

<table>
<thead>
<tr>
<th></th>
<th>Observed</th>
<th>Expected</th>
<th>(O-E)^2</th>
<th>(O-E)^2/E</th>
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<tr>
<td>Patent Introduced</td>
<td>20</td>
<td>11.3</td>
<td>75.16</td>
<td>6.63</td>
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<tr>
<td>Company R &amp; D Expenditure</td>
<td>8</td>
<td>11.3</td>
<td>10.89</td>
<td>0.96</td>
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<tr>
<td>Company Turnover</td>
<td>6</td>
<td>11.3</td>
<td>28.09</td>
<td>2.98</td>
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</tbody>
</table>

   Test Statistics
   Chi-squared = Σ (observed-expected)^2/ (expected)
   Chi-squared = 10.57
   Level of significance (maximum error) 0.01
   No. of rows 3
   Degrees of freedom n-1 2
   Critical chi square stat 9.210
   Conclusion: Since the calculated Chi-squared is greater than the Critical chi square stat. It is highly significant and rejects the null hypothesis.

2. Implication of amended patent act has resulted in improving Economic status of Indian pharmaceutical companies.

   **H0**: Implication of amended patent act (increase in no. of patent used by company) does not improve Economic status of Indian pharmaceutical companies.
H1: Implication of amended patent act (increase in no. of patent used by company) does improve Economic status of Indian pharmaceutical companies.

**CALCULATION:**

<table>
<thead>
<tr>
<th>Observed:</th>
<th>Turnover Less than 1000 cr.</th>
<th>Turnover Greater than 1000 cr.</th>
<th>Total</th>
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<tr>
<td>No. of patent</td>
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<td>20</td>
</tr>
<tr>
<td>100 &amp; above</td>
<td>5</td>
<td>6</td>
<td>11</td>
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<tr>
<td>Total</td>
<td>18</td>
<td>13</td>
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<table>
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<th>Expected:</th>
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<td>100 &amp; above</td>
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</tr>
<tr>
<td>Total</td>
<td>18</td>
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<td>31</td>
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Test Statistics
Chi-squared = Σ (observed-expected) 2/ (expected)
Chi-squared = 1.113422687
Level of significance (maximum error) 0.5
No. of rows 2
No. of column 2
Degrees of freedom (r-1)*(c-1) 1
Critical chi square stat 0.454936425
Conclusion: Since the calculated Chi-squared is greater than the Critical chi square stat. It is significant and rejects the null hypothesis.

**10. Finding**

IP scenario of Indian Pharmaceutical Industry has changed significantly since 1st January 2005. The innovation capability of the domestic pharmaceutical industry has witnessed an increase in both, research and patenting. The number of patent applications filed in the Indian Patent Office has consistently increased with annual growth
averaging 9% per annum from 2005-2010. Over the entire period a total of 16459 applications in Drugs have been filed. The leading players in the Indian pharmaceutical market comprise both India-based and MNCs. Top 10 Assignees who have been granted maximum number of product patent by Indian Patent Office during 2005-2010 includes Aventis Pharmaceuticals (190 Patents) followed by Roche (146 Patents) and Novartis (136 Patents). India's leading pharmaceutical companies are competing not only in the domestic market, but also in the global market for both generic drugs and original products. India's top five pharmaceutical companies, who have been granted majority of product patents from 2005-2010 are Glaxo, CSIR, Dr. Reddy's, Cipla and Cadila. These companies manufacture a wide range of generic drugs (branded and non-branded), intermediates, and active pharmaceutical ingredients (APIs). So there is positive impact of amended patent act 2005 in India.

**Impact on business** - TRIPs will transform the legal & business framework in India. It is going to fundamentally alter competitive equation for starters; better intellectual property protection will facilitate the transfer of technology. Better intellectual property protection will facilitate transfer of better technology. Foreign firms are often accused of transferring outdated technologies to their Indian partners, but it is often forgotten that a lax intellectual property rights regime does not offer much incentive to do otherwise. Quality of intellectual property protection improves expenditure on R & D by industry as a whole will climb. The switch from process patent to product patent will transforms the pharma industry & will the TRIPs agreement expanding the scope of patent protection to include all fields of technology.

**Effect of change in patent regime**

**Effect on transnational’s:**

1. Investment will granted better intellectual property rights protection,
2. Their research and development center can be set up in India.
3. Technology transfer to Indian joint ventures will be safer.
4. Patents held by global patents will be recognized in India.

**Effects on consumers**

1. Global product will become more easily available in India.
2. Better product will be available to the consumer.
3. More products will meet higher quality standards.
4. Prices of some patented product will increase.

**Effects on research and development**

1. Research results must be patented before publication.
2. Technologies development will be licensed out.
3. Corporate and lab will collaborate on research and development.
4. Commercialization of research will earn royalties to fund research and development.

**Effects on government**

Policies are conforming to the new regime must be created.
1. The process of granting patents must be speeded up.
2. Patent application fees will become a source of revenue.
3. Penalties for violation of patent laws will have to be hiked.

**Trends in pharmaceutical R&D**

![Graph showing trends in pharmaceutical R&D](image)

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