



An analysis of patent act, 1970 and its implications on pharmaceutical industry

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Abstract

The Indian Patents and Designs Act, 1911 was formulated as the right given to inventors for first time independently. The law made by the Britishers was in force in India. And it continued till date. Patents are the most important field in Intellectual Property Rights. From past years the pharmaceutical companies after taking a lead and this resulted in the rise for the drugs to be patented. But everything has pros and cones. Similarly, the need for the medicines to be patented there arises the need to elaborate the concept of patent law. Patent analysis is a well-known valuable approach that uses patent data to derive information about growth in a particular technology and for planning technology development strategies. Such analysis is also a useful way of examining continuous flow of knowledge from science to technology particularly for emerging technologies where no historic data is available.

Keywords: patent, patent, independently, Designs

1. Introduction

The first Patent protection in India came into light in 18th century. The legal protection to the said patents is not a new concept, it is one and half century old. The Patent Rights has very vast historical significance. It was traced back in 1856. The inventors who are the exclusive manufacturers are granted the special privilege so that their efforts should not be misused by anyone else. The period was decided, the said act was later repealed because it was passed in haste and had many loopholes in it. It was repealed in 1857. Moreover, the major reason behind it was that it was without the approval of the sovereign. The modifications were done in 1859 in the said act. The period was as such that is 14 years^[1].

1.1. History of Patents Act, 1970

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Patents are the most important field in Intellectual Property Rights. From past years the pharmaceutical companies after taking a lead and this resulted in the rise for the drugs to be patented. But everything has pros and cones. Similarly, the need for the medicines to be patented there arises the need to elaborate the concept of patent law. There need some changes in Indian patent law so that the drugs should also be given the opportunity to get such exclusive rights. There are many cases in Indian law that the there is much difficulty in granting the patents to the pharmaceutical industries. The process for granting the patent to such industries is a herculean task. The approval is very tough and the conditions that are being specified the Patent Act are not up to the mark and covers a very wide range. In the last 48 years, the industries faced many difficult situations related to the imported drugs that were sold out in bulk. They were

produced by using the high technology. India is on third rank in technology and in the quality and range of medicine that were manufactured. The industry produces medicines, which are comparable to the best in the world.

Almost 70% of the indigenous demanded for large stock of drugs and almost the entire demand for formulations are being connected through domestic production. This industry today has the capability of reducing the wide range of bulk drugs, covering a large spectrum of technologies and almost all formulations. In fact, the country is almost fully self-reliant in terms of formulation technology. In the case of bulk drugs, the technology includes those for sulpham drugs, vitamins, and a number of new synthetic drugs like Flumequinie, Phelfloxacin, Rampril, Keterolc etc. The industry today is quite widely distributed among the foreign companies, public and private sector units. There are as many as 17000 odd units, big and small engaged in the manufacture of drugs.

Of these, nearly 500 are in the organized sector, 8000 are loan licensees and rest is a small-scale unit. The 1990s have been healthy for the Indian pharmaceutical industries. The production has grown^[2].

Without adjusting for inflation at 18% per annum- from Rs.4600 Crores in 1992 to Rs. 15000 crores in 1998. Despite such rapid growth, and its scope in covering 15% of the world's population, the Indian pharmaceutical industry remains small accounting for only one per cent of the global industry turnover. No single player dominates in fact more than 20000 pharmaceutical companies compete in the market and no one company has a market share greater than 9 percent.

The industry, which has a considerable measure of health care, places it in a pivotal position in the socio - economic development of the country. It serves a market where a social bias has to be reflected in its functioning. The industry has been the subject of much criticism, arising often on emotional and political reasons on account of high prices, excessive profits and foreign monopoly. An elaborate range of government controls regulates the

functioning of the industry. In order to present its case by providing adequate information on pertinent issues and interpret itself to the public, the press, and the medical profession. Parliament and the government, the pharmaceutical industry formed a trade association in 1965 called the Organization of pharmaceutical Producers of India (OPPI).

2. An Analysis and the Patent Act 2005 Implications

From a large-scale importer of finished drugs in the pre-war period and a mere processing industry with a production value of Rs.10 Crores at the time of the country's independence, it has grown into the largest chemical based industry manufacturing basic drugs out of primary raw materials and intermediaries, with an output of the finished products worth Rs. 300 Crores.

The industry began its development in an organised manner only in 1948. Until then it presented a picture of individual enterprises, sporadic in origin and in various stages of their growth. Though the national government which into power at that time started to give the industry a definite shape by including it within the larger frame work of the country's overall plan for industrialization, as detailed in the first five year plan (1951-56), it was only in the second plan that the industry was given its rightful place. In 1948, a survey was made of the country's industrial potential in every sector and a program of development was chalked out. The goals in different fields to be reached in a sequence of progressive self-reliance were set.

The pharmaceutical industry, it was felt, needed a regulated and planned development. With a view to developing it as an integrated industry the national government set up in 1953 a pharmaceutical inquiry committee and placed it in a classification that allowed both the government and private enterprises to set up manufacturing units^[3].

(Development and Regulation) Act and put under the guidance of the Directorate General of Technical Development (DGTD). To ensure its functioning efficiently, a co-ordinating council was formed with members representing different interests concerned with drugs, including the medical profession.

At the commencement of the First five-year plan the pharmaceutical industry consisted of over 1700 manufacturing units, in the organised sector forming the core of the complex and the balance in the small-scale sector. Their total capital investment amounted to about Rs.24 Crores. Since then the industry has forged ahead. A significant feature of the industry's growth is that throughout, the manufacture of basic drugs has been accorded top priority with the result that the industry today is self-sufficient to a large extent in its raw material requirement. An important feature of the industry is the establishment of units in the public sector. The Hindustan Antibiotics Ltd., at Pimpri and the Indian Drugs and Pharmaceuticals Ltd., with its antibiotic plant at Rishikesh, synthetic drug plant at Hyderabad and surgical instrument plant at Chennai are the major units in the sector. When the Rishikesh and Hyderabad plants reach their full rated capacity very substantial increases in the output of the basic drugs will have been achieved. The public sector consists mainly of two major units viz., the Indian Drugs and Pharmaceuticals LTD (IDPL) and Hindustan Antibiotics LTD (HAL) which are engaged in the production of essential basic drugs like antibiotic and synthetic drugs and

formulations required for the National Health Program. The investment in these two units amounts to Rs.70 Crores about one third of the total investment in the industry. IDPL, which has Antibiotics plant at Rishikesh and Synthetic plant at Hyderabad has been operating on technology, imported from Russia through inter-government contracts and with loan assistance for the purchase of capital equipment and also technical assistance. The drug industry in India today is broadly composed of two sectors:

1. Public sector
2. Private sector

Which can be further divided into:

Large scale (better known as organized sector) and small sector Drug manufacturing consists of two distinct activities: manufacture of bulk drugs, which is capital intensive, with an investment turnover ratio of 1:1 to 1:1.5. Manufacturing of formulations consists of conversion of bulk drugs, (imported or indigenous) into dosage forms. While capital investment in this activity is comparatively less, it however, requires highly sophisticated marketing and merchandising practices thus making it very much market intensive. As of 1974-75, the total production of the DPI is estimated at Rs.594 Crore. Of this, share of the Indian sector including the public sector came to Rs.257 Crore or a little over 43 percent of the total. It may be noted that the combined total of bulk drugs and formulations in the mid-seventies added up to Rs.708 Crores. Of this, the value of formulations came to Rs.586.67 Crore, or about 83 percent, as against 17 percent in the case of bulk drugs. Thus, in the mid-seventies, the Indian sector had a larger share than the foreign sector. The ratio of formulations to bulk drugs came to 1:4:49 and 1:5:33 for the Indian sector and foreign sector respectively; the difference in the ratios between the two sectors was rather negligible. During the latter half of the seventies, the proportions of bulk drugs to formulations by the Indian sector suffered a 42 significant decline from 55.56 percent to 42.24 percent whereas the foreign sector increased its share from 44.44 percent to 57.76 percent^[4].

The data regarding the bulk drugs production for the mid-eighties revealed that the bulk drugs production of MNCs have further deteriorated. Close to 40,000 to 60,000 formulations are available as on date, the peculiarity of drug marketing being that it is the doctor who is the actual target of the high pressure selling." With a low level of per capita income as well as the unequal distribution of income, the size of the Indian market is small". With the government able to purchase a bare 1-% of the total amount of the pharmaceutical products marketed, it is private purchases that hold the key. Therefore, the skewed pattern of demand for drugs, identical to the skewness in income distribution ensures the proliferation of inessential drugs in the market. There are about 250 bulk drugs or active ingredients of medicines being produced in India. An equal number is imported. From these 500 odd bulk drugs, about 250 companies in the organized sector manufacture nearly 20,000 formulations or dosage forms in different strengths and packs. In addition, there are several thousand small manufacturers who produce about an equal number or perhaps more of the same drugs in much dosage form strengths and packs. In fact, the number of basic drugs used in our country is less than any developed countries. Even the number of drug forms is not different. The number of companies proliferated by the mid-eighties to about 24,000

and of these less than two per cent of them were in the organized sector whose activities were controlled and monitored by the Central government. The balance was in the small-scale sector under the control of state governments. Even though the Drugs control authority was responsible for the quality of products marketed by all sectors, it was impossible to continuously police over 60,000 packs from 24,000 companies, spread all over the country. The economic reforms announced in 1991 have often been heralded as an opening of a new chapter for the Indian industry. Chandrasekar and Kaliyamoorthy (1999) opined that this industry thrives on factors like low cost manufacturing, price competitiveness, cheap skilled labor, raw materials and economies of scale among others. According to VK Sareen (1999) India is in a position to meet 70 percent of the country's requirements of bulk drugs and almost all the demands for the Formulations.

There are more than one thousand bulk drug manufacturers and more than 50000 formulations which are available to the public through 5 lakh chemists all over the country.

D.Bhadury (1987) suggests that the process of consolidation through mergers and acquisitions has become a common phenomenon in the global pharmaceutical Industry. This process has started in India too. As the market grows and profitability improves, Indian pharmaceutical companies, either on their own or more likely in association with international companies, could become a source of low-cost manufacturing as well as R&D. The Indian economy has seen the rise in merger and acquisition activity since the liberalization process gathered momentum from 1991 onwards and pharmaceutical industry is not an exception. The number of M&As has been increasing and each industry is witnessing change. Vinayshil Gautam and Vinnie Venma (1995) while analyzing the various industries, the privatization of industries like power steel and telecom has thrown open new opportunities. The spate of M&As has increased due to the changes in the economic policies. Companies have gone in for M&As to exploit the opportunities thrown open by the environment. They have gone in for strategic alliances, marketing pacts, and R&D arrangements, forward and backward integration deals through franchising contracting and licensing in order to achieve their ambitions.

Vinayshil Gautam and Vinnie Verma," found that related M&As are those are in line with the current activities of an organisation i.e., same product line or a backward/forward integration viz., buying. The same source of raw materials or distribution strength in the same area of operations. During the year 1993-96, the number of M&As in pharmaceuticals are seven, which takes the third position among all the industries. The acquisition of Tata Phamia by Merind suggests increasing the market presence, a larger field force, wider distribution and a strong presence in the markets of northeast India and Russia ^[5].

In fact as is evident from the earlier surveys on the industry, V. Venkateswaran (1981) the pharmaceutical sector has made significant progress both in the public and private sectors despite many difficulties in the shape of non-availability of raw materials, power shortage and strained labor relations. According to Roy Pinto (1998) the sector can be broadly divided into 168 segments of which the top 30 make up 67 percent of the total Indian pharma industry of Rs.10, 000 Crores.

The United Nations Centre in Transnational Corporations

(1984) in their study quoted that the structure of pharmaceutical market is admittedly monopolistic or oligopolistic.

Exports have risen from a meagre Rs.3 Crores in 1965-66 to Rs.4978 in 1997-98 as is evident from the above table. Exports of formulations by the end of the eighth five-year plan are estimated to be around Rs.4.5 billion. India's major export destinations for bulk drugs and formulations include the Russian Federation, Germany, the USA and Switzerland, with Russia taking a 25 percent share of these products.

Michael Porter (1986) asserted that there are two basic steps to attain the competitive advantage. First firms may pursue a strategy of low costs, which enables them to offer similar products at lower prices than those charged by the competitors. Second, firms may pursue a strategy of differentiation - that is, one of trying to convince customers that their products have unique benefits that offset their premium prices. Both these strategies have the same effect: They increase the perceived benefits of the product. M.A.McGinnis and M.R.Ackelsberg (1983) identified the need for innovation in organizations. Innovation management means creating an organizational climate that favors innovation, creating an innovative organization and harnessing individual innovation. Effective innovation management depends on the firm capitalizing on the external environment, creating a firm and a climate favorable to innovation, and effectively managing creative individuals. Raj Smarta, (1999) a leading pharmaceutical consultant mentioned for any organization, innovation is a distinctive capability that yields competitive advantage and aids performance. Managing innovation is expensive and risky. When innovation is highly appropriate and timely the innovating firm as a winner, takes the full cake. This is frequently the case in the pharma industry. In markets, such as these, potential participants need to carefully consider whether they wish to enter at all. If there are many players, it is quite possible that their combined expenses will exceed the value of the prize for which they are competing. A variety of strategies can be applied to overcome these difficulties: Commitment from the company

- Timing and cost effectiveness
- Investment in basic research
- Evolution through exploitation of gene therapy and cell therapy is likely to take charge of future innovations EPP team (1999) conducted a study to find the importance of innovation in the pharmaceutical industry and came up with the findings that if the Indian pharmaceutical industry has to emerge as a global player, the crux is innovation. This includes protection of intellectual property, fiscal policies towards free market in pharmaceuticals, government support of basic research in country on specific diseases and indigenous medicine, strengthening regulatory systems:

Dr. R.K. Srivastava,"How to make an effective marketing plan to combat competition", suggested that the marketing plan be like a religious book to any marketing personnel. Unfortunately, due to lack of understanding, no involvement, and little follow-up in many companies it has become like rituals, which is performed by few individuals. In fact, marketing plan recommends strategies but it do not

justify the recommendation. It should hence discuss in detail about each strategy and its likely impact with respect to sales and profit. It should justify and rationalize the reasons for adopting such strategy. The implementation of the marketing plan is possible if only the people in preparation of the marketing plan are also included and also train the concerned people and review on a quarterly or monthly basis the performance. Companies must improve in this area which is very much neglected but very important aspect. It can take the company to the top or paralyze it. Neil Borden (1964) provided the idea for marketing mix and mentioned that marketing driven company's control and integrate a variety of complex business activities that are commonly referred to as the marketing mix. In the traditional approach to marketing, the marketing mix is the set of tools and techniques- the product, its pricing and distribution and its marketing communication - used by a company to market its product at a profit Kay (1993) found that long term competitive advantage derives from capabilities "which other firms lack", that are 'underpinned' by 'supporting strategies' in a specific 'industry' to gain market advantage against specific rivals^[6].

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Raj Smarta identified that traditionally positioning strategies in the pharmaceutical industry have been exclusively built around the technical aspects of the product. He advocated with the relative advantage on the product not forthcoming; companies have to rely on several other positioning measures like related to a specific attribute or to Use or application etc.

According to Suresh Sukheja (1999), product management in pharmaceutical industry is the most important function. He narrates the duties of product managers is to develop and promote the market share of his products by adopting various marketing techniques as well as strategic positioning of products, thereby putting into use the knowledge and information of the product manager concerned. In these days, where a plethora of brands is in existence in the market, a product manager's job is one of the toughest and it takes a lot of talent to successfully devise a strategy for any product.

3. Conclusion

Pharmaceutical market is the most trending and growing field in the form of development and profit shares. India is one of the largest hubs of the global pharmaceutical market. Total contribution of the Indian Pharmaceutical market in the total business is US \$ 6 billion. Indian market is growing very high pace, and many companies contribute to the ever-increasing drug and pharma demand. From the above research of the statistics of the different pharmaceutical companies, it was found that companies are giving each other a tough competition. Along with this, number of patents filled by different companies has been increasing ever since.

Companies today stick to the Darwin's principle of survival of the fittest. Companies like Torrent pharmaceuticals and

Cadila Healthcare Limited have highest expenditure in R&D, and their new patent filing percentage have been increasing in the past few years. Percentage of revenue for these companies also increased in last few years. Company's overall performance is determined by the Research & Development of the company. From statistics, it has been found that Indian companies have filed maximum number of patents in the last five years. This makes the pharma market of the India a very famous destination for the companies to establish in India.

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