RESEARCH REVIEW JOURNALS
Volume-04
Issue-06
June-2019

ISSN: 2455-3085 (Online)
RESEARCH REVIEW International Journal of Multidisciplinary
www.rrjournals.com[UGC Listed Journal]

Design and Development of Pharmaceutical Industry and its Patent System

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ARTICLE DETAILS

Article History
Published Online: 12 June 2019

Keywords
Pharmaceutical industry, product patent, R&D, IPR department, Intellectual Property Rights.

ABSTRACT

Patent is one of the major forms of Intellectual Property Rights (IPRs) used in the pharmaceutical industry. Trade mark, industrial design, geographical indication and copyright are other forms of IPRs available in India. Grant of patent in India is governed under the Patents Act, 1970. Significant changes like provision of product patents and increase in the term of patent to 20 years were introduced in the Indian patent law, after India signed TRIPS (Trade Related Aspects of Intellectual Property Rights) agreement in 1995. This review provides a brief overview of development of patent law in India as a consequence of TRIPS agreement. Criteria of patentability and different types of pharmaceutical patents currently being granted in India are described with the aim to provide the fundamental knowledge of pharmaceutical patenting to the researchers. Other relevant provisions related with patenting of pharmaceuticals like transfer of the patent rights, compulsory licensing etc.

1. Introduction

Patents are exclusive property rights in intangible creations of the human mind. They exist only as provided in the laws of sovereign states, and can be enforced only to the extent that application has been made and a patent granted covering the territory of an individual state. Patent rights are limited in duration, with the global standard being 20 years from the date of application. The new product, article of manufacture or process described in the patent application must be something that has never been previously disclosed anywhere in the world and something that would not be obvious to a person ordinarily skilled in the field involved. Determinations of whether these requirements have been met are made by comparing the claims of the patent applicant against the body of published literature in the field, including previously issued patents. This process is called examination, and it assures that no one is able to claim patent rights on anything that already is existence. Patents work differently indifferent industries. In the electronic industry patents are often shared among competitors through pooling or cross licensing. This sharing is necessary because a given product often contains many patented technologies. However, in the pharmaceutical, chemical and biotechnology industries the patent normally equals the product, and protects the extensive investment in research and clinical testing required before placing it on the market. Patent protection for chemical and pharmaceutical products is especially important compared with other industries because the actual manufacturing process is often easy to replicate and can be copied with a fraction of the investment of that required for the research and clinical testing.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.

2. Literature Review

Ravi Kiran, Sunita Mistra (2011) which center around the changed situation because of Amended Patent act 2005. India as a signatory part marked TRIPs for protecting item patent, primer India refused for the change. This can be a result of n number of reasons like if item patent winds up compulsory licensing may get influenced, cost of solution may increment and so forth patented item resembles an asset to the organization. It builds profitability of respective organization and future rivalry or turnover won't be discounted of item yet it will be on the quantity of patent an organization is holding. Indian residential and also worldwide organization comprehended the need of research activity to make due in market and these days the majority of them are changing from impersonation to innovation by expanding R and D activity to support in advertise.

V. K Shrivastava (2007) has expounded on Parent Law and Indian Pharmaceutical Industry. As per him the law identifying with patents is contained in the patents Act 1970,

which came into constrain on April twentieth, 1972. This Act was altered twice in 1999 and 2002 preceding the most recent amendment in 2005. The amendments were completed to meet India's obligations under the Agreement on TRIPs, which shapes a piece of the understanding establishing the WTO. The primary arrangement of amendments was acquainted in 1999 with set up a system for tolerating item patent applications covering pharmaceutical and horticultural synthetic concoctions from January 1, 1995 (otherwise called the letter box provisions) and to give selective promoting rights if certain conditions are satisfied. While the second amendment which was presented in 2002 gone for carrying the Patents Act in similarity with all the important provisions incorporated into the TRIPs Agreement, notwithstanding a lone exception of extending the item patent administration in the field of pharmaceuticals, agrochemicals and sustenance.

B.C. Nirmal (2007) has expounded on Indian Pharmaceutical Industry and The New Patent Regime. As indicated by him the pharmaceutical business is very much created and proficient to deliver and offer for all intents and purposes every one of the drugs required in the nation. Indian organizations supply an expansive number of non-specific mass drugs and their formulation to the worldwide market. As per an investigation, 67 percent of the meds created in India are sent out to creating nations. The main organizations in India have gained more than 20 organizations on board and the Indian business has now turned out to be worldwide in specific portions. The biggest Indian organizations have deals turnovers of $ 50 million to $1.2 billion. Despite the fact that this size of offers turnover is moderately little when contrasted with yearly offers of the main MNCs of US, Europe and Japan which are in the scope of $ 5 billion to $ 50 billion, the position of the Indian business as a worldwide player is broadly recognize and Indian organizations have satisfactory capabilities to make riche position in the worldwide market in the days to come.

S.B. PURANIK (2010) Patent is a licensed innovation right identifying with creations and is an allow of restrictive appropriate, for constrained period, given by the Government to the patentee, in return of full exposure of this development, for barring others, from making, utilizing, offering, bringing in the patented item or process delivering that item for those reasons. The reason for this framework is to encourage creations by advancing their protection and usage in order to add to the improvement of industries, which thusly add to the advancement of mechanical innovation and to the transfer and dispersal of technology. Under the framework, Patents guarantee property rights for the innovation for which patent have been without a doubt, which may to a great degree profitable to an individual or a Company. Patent right is regional in nature and a patent got in one nation isn't enforceable to other nation. The creators/trustees are required to document isolate patent applications in various nations for acquiring patent in those nations.

Dr. Sarika Zambad (2014) The Indian pharmaceutical organization has been worked from an industry that duplicates patent drugs and fabricates them economically. Presently it is tallied among the industries that are fuelling India's economic growth and holds huge potential. Indian-based pharmaceutical organizations are likewise anticipated to increase considerable piece of the overall industry on the planet. It positions third around the world, as far as technology, quality and scope of pharmaceuticals produced. Indian Pharma Company satisfies around 70 percent of the nation's request all together. Presently, it's estimated to be worth US$4.5 billion, and is developing at about 8 to 9 % every year. Because of revised patent act there are an arrangement of changes occurred in Indian pharma industry. The essential target of this paper is to think about essentialness of the changed patent follow up on pharma industry. The paper additionally permits investigation of the extent of corrected patent act.

Vipin Mathur (2012) Patent is one of the significant types of Intellectual Property Rights (IPRs) utilized in the pharmaceutical business. Trade stamp, industrial outline, geological sign and copyright are different types of IPRs accessible in India. Allow of patent in India is administered under the Patents Act, 1970. Noteworthy changes like arrangement of item patents and increment in the term of patent to 20 years were presented in the Indian patent law, after India marked TRIPS (Trade Related Aspects of Intellectual Property Rights) assention in 1995. This audit gives a concise diagram of advancement of patent law in India as a consequence of TRIPS assention. Criteria of patentability and distinctive kinds of pharmaceutical patents as of now being conceded in India are portrayed with the mean to give the crucial information of pharmaceutical patenting to the researchers. Other pertinent provisions related with patenting of pharmaceuticals like area 3(d), transfer of the patent rights, compulsory licensing and so forth are clarified with reasonable illustration.

3. Indian Pharmaceutical Company

Indian pharmaceutical organization is in the front-side position of India's science based industries with far reaching capabilities in the complex field of medication assembling and technologies. From straightforward migraine pills to sophisticated antibiotics and complex cardiovascular mixes, relatively every sort of medication is currently made indigenously. The Indian pharmaceutical organization has been worked from an industry that duplicates patent drugs and fabricates them cheaply. Presently it is tallied among the industries that are powering India's economic growth and holds huge potential. Indian-based pharmaceutical organizations are additionally anticipated to increase considerable piece of the pie on the planet before the decades over. It positions third around the world, as far as innovation, quality and scope of pharmaceuticals made. The business is estimated to have produced income worth US$13.1 billion in FY 2011(1). Indian pharmaceutical organization satisfies around 70 percent of the nation's interest for mass drugs; medicate intermediates, pharmaceutical formulations, synthetic substances, tablets, containers, orals and injectibles. (2) Currently, it's estimated to be worth US$4.5 billion, and is developing at about 8 to 9 percent every year. (3)

4. Patent Regime In India

The Patent Act of 1970 saw the mass departure of the multinational organizations (MNCs) as it perceived just process patents. Indian organizations had the opportunity to recreate drugs made by patent holding organizations without paying any sort of charge. They were protected by the patent demonstration to legitimately figure out universally patented drugs and offer it inside India and furthermore in those business sectors that did not fit in with sedate patents.

In view of altered patent Act 2005, Indian pharmaceutical organization has taken a tremendous lead. Before the amendment in Patent act 2005, Section 5 of the Indian Patents Act, 1970 explicitly allowed just process patent and disallowed item patents. After the implementation of TRIPS, the Patents amendment Act, 2005 revoked it and along these lines offered approach to item patents also. Item patent is a much strict limitation than process patent. The contrast between process patent and item patent is that under a process patent, medication or drugs which have been patented can be produced by another manufacturer however by utilizing an alternate process. Be that as it may, in an item patent drugs which have been patented can't be fabricated by any process. In consequence of India consenting to the TRIPS Arrangement and WTO India acknowledged the item patent from 1-1-2005 as per the obligation under Article 27(1) of the TRIPS.

5. Intellectual Property Legislations In India

India is an individual from every worldwide tradition. The obligation of the part state emerging out of the traditions can be authorized based on reciprocity as it were. No privilege or obligation is enforceable singularly. Subsequently to pass possess laws on Intellectual property is in light of a legitimate concern for each nation. In 1999, a circumspect section of significant legislations concerning protection of Intellectual property rights in harmony with global practices and in consistence with India's obligations under TRIPS. These incorporate,

1. The Patents (Amendment) Act, 1999 to alter the patents demonstration of 1970 that accommodates foundation of a letter drop framework to record patents and accords selective promoting rights for a long time.
2. The Trade marks Act, 1999 which canceled the Trade and Merchandise Act, 1958
3. The Copyrights (Amendment) Act, 1999.
4. A sui generis enactment for the protection of geological indications called the Geographical Indications of Goods (Registration and protection) Act, 1999.
5. The Industrial Designs Act, 2000 which replaced the Designs demonstration, 1911.
6. The patents (Second Amendment), 1999 further to revise the Patents Act, 1970.

6. Patents and the Future of the Indian Pharmaceutical Company

The absence of item patent protection for pharmaceuticals and agrochemicals drove numerous multinationals to restrain their portfolios to patent expired items or a couple of chosen patented items. This brought about a disintegration of their piece of the pie in light of the fact that

1.Nearby manufacturers presented the most developed prescriptions through figuring out.
2. Remote firms were required to pay eminences for global drugs, while Indian organizations could get to the most up to date molecules from everywhere throughout the world and reformulate them available to be purchased in the local market.

7. Challenges

- Manpower
- Early stage funding
- There is serious scarcity of trained work force, the main arrangement being recruiting crisp graduates and preparing them at work. Such a situation prompts wild poaching of trained individuals from different organizations.

8. 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.

9. 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.

10. Impact on pharmaceutical industry after product patent regime

The 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.

11. 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 form multinational pharmaceutical 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 thepatents, 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- size 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.

12. Conclusion

The Indian pharmaceutical organization until 2005 will be occupied with generic item development thus there will be no significant action in patenting in India. In 2005, the Indian Patent Act will be corrected to incorporate an 'item patent' regime to make Indian patent law consistent with TRIPs. The moved the Indian pharmaceutical organization's concentration from generic items to research based. The Indian Patents Act, 2005 presented item patents in India and denoted the initiation of another patent regime went for securing the Intellectual property rights of patent holders. The end which turns out from research will be that these organizations will be realized the need of R&D in post TRIPS period and they will be expanding their R&D Activity.

The ends as indicated by the research study will be that revised patent Act 2005 will be valuable to Indian pharmaceutical organization, intellectual property right framework will be helped Indian pharmaceutical organizations in growth, Indian intellectual property right framework will be easy to use to Indian pharmaceutical organization and the way toward filling patent is easy to use to Indian pharmaceutical organization.

In the pharmaceutical part it will be patents that are particularly essential in appropriating the returns to R&D. This will be on account of once the originator; leap forward drug is

created through lengthy and generally expensive R&D forms, the time, capital and effort associated with duplicating usually insignificant. Be that as it may, in the meantime it will build cost of treatment to regular man. In the event of generic pharmaceutical manufacturing when the letter drop applications will be cleared and patents granted, recently presented generics in the Indian market may must be pulled back. Expenses to the patient will at that point unavoidably rise. New drugs that rise in the international field will be accessible to Indian patients just from the patent holder. The end which turns out from the study is that if there will be reasoning in patented existence of medicinal item something close to 5 to 15 long periods of patented life, it will result in the financial treatment of the poor populace.

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