

PATENTS ISSUES IN INDIAN PHARMACEUTICAL INDUSTRY

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Abstract- Intellectual Property Rights (IPR) has been defined as ideas, inventions, and creative expressions based on which there is a public willingness to bestow the status of property. IPR provide certain exclusive rights to the inventors or creators of that property, in order to enable them to reap commercial benefits from their creative efforts or reputation. There are several types of intellectual property protection like patent, copyright, trademark, etc. Patent is recognition for an invention, which satisfies the criteria of global novelty, non-obviousness, and industrial application. IPR is prerequisite for better identification, planning, commercialization, rendering, and thereby protection of invention or creativity. Each industry should evolve its own IPR policies, management style, strategies, and so on depending on its area of specialty. Pharmaceutical industry currently has an evolving IPR strategy requiring a better focus and approach in the coming era. Indian pharmaceutical industry is growing at the faster rate. On the other hand, Indian pharma companies are looking for global business opportunities in the form of export business, contract research and clinical trials. Many Indian companies started realizing the importance of Intellectual Property Rights. The volume of money spent on R&D also growing to a greater extent. There are many challenges faced by the Indian pharma companies' right from their initial investment to strengthen their R&D and up to obtainment of Patent and other IP Protection for their new innovations. There are many legal formalities are to be carried out for drug discovery, documentation, clinical trials etc., Cost of investment, expiry of patented drugs, lack of clinical trials, more legal formalities, complications in obtaining IP Protection are the major problems faced by Indian Pharmaceutical Companies. This study mainly focused on both the problems encountered by the companies as well as the opportunities available for Indian Pharmaceutical Companies in the form of IPR. The common problems associated with IPR with special reference to Indian Pharma Companies led to greater opportunity for this study. As Indian pharmaceutical companies start truly investing in R&D and developing their own molecules available for patenting, it is undeniable that they will want to protect their innovation through patents. Therefore, the Indian government ought to be promoting and protecting patents of multinational companies too. Patent protections and other forms of Intellectual Property (IP) rights are important for industry and R&D. Without strong protections companies, especially pharmaceutical companies do not have incentives for R&D or developing new, innovative drugs.

Keywords- Intellectual Property Rights, Patent, Research & Development, Clinical Trials, Copyrights, Generic Drugs etc.,

I. INTRODUCTION

Intellectual Property Rights (IPR) has been defined as ideas, inventions, and creative expressions based on which there is a public willingness to bestow the status of property. IPR provide certain exclusive rights to the inventors or creators of that property, in order to enable them to reap commercial benefits from their creative efforts or reputation. There are several types of intellectual property protection like patent, copyright, trademark, etc. Patent is recognition for an invention, which satisfies the criteria of global novelty, non-obviousness, and industrial application. IPR is prerequisite for better identification, planning, commercialization, rendering, and thereby protection of invention or creativity. Each industry should evolve its own IPR policies, management style, strategies, and so on depending on

its area of specialty. Pharmaceutical industry currently has an evolving IPR strategy requiring a better focus and approach in the coming era.

Brief History of Intellectual Property Rights

The laws and administrative procedures relating to IPR have their roots in Europe. The trend of granting patents started in the fourteenth century. In comparison to other European countries, in some matters England was technologically advanced and used to attract artisans from elsewhere, on special terms. The first known copyrights appeared in Italy. Venice can be considered the cradle of IP system as most legal thinking in this area was done here; laws and systems were made here for the first time in the world, and other countries followed in due course. Patent act in India is more than 150 years old. The inaugural one is the 1856 Act, which is based on the British patent system and it has provided the patent term of 14 years followed by numerous acts and amendments.

Types of Intellectual Properties and their Description

Originally, only patent, trademarks, and industrial designs were protected as 'Industrial Property', but now the term 'Intellectual Property' has a much wider meaning. IPR enhances technology advancement in the following ways:

- a. it provides a mechanism of handling infringement, piracy, and unauthorized use
- b. it provides a pool of information to the general public since all forms of IP are published except in case of trade secrets.

IP protection can be sought for a variety of intellectual efforts including Patents

- i. Industrial designs relates to features of any shape, configuration, surface pattern, composition of lines and colors applied to an article whether 2-D, e.g., textile, or 3-D, e.g., toothbrush
- ii. Trademarks relate to any mark, name, or logo under which trade is conducted for any product or service and by which the manufacturer or the service provider is identified. Trademarks can be bought, sold, and licensed. Trademark has no existence apart from the goodwill of the product or service it symbolizes
- iii. Copyright relates to expression of ideas in material form and includes literary, musical, dramatic, artistic, cinematography work, audio tapes, and computer software.
- iv. Geographical indications are indications, which identify as good as originating in the territory of a country or a region or locality in that territory where a given quality, reputation, or other characteristic of the goods is essentially attributable to its geographical origin.

A patent is awarded for an invention, which satisfies the criteria of global novelty, non-obviousness, and industrial or commercial application. Patents can be granted for products and processes. As per the Indian Patent Act 1970, the term of a patent was 14 years from the date of filing except for processes for preparing drugs and food items for which the term was 7 years from the date of the filing or 5 years from the date of the patent, whichever is earlier. No product patents were granted for drugs and food items.

A copyright generated in a member country of the Berne Convention is automatically protected in all the member countries, without any need for registration. India is a signatory to the Berne Convention and has a very good copyright legislation comparable to that of any country. However, the copyright will not be automatically available in countries that are not the members of the Berne Convention. Therefore, copyright may not be considered a territorial right in the strict sense. Like any other property IPR can be transferred, sold, or gifted.

II. STATEMENT OF THE PROBLEM

The number of purely Indian pharma companies is fairly low. Indian pharma industry is mainly operated as well as controlled by dominant foreign companies having subsidiaries in India due to

availability of cheap labour in India at lowest cost. Most pharma companies operating in India, even the multinationals, employ Indians almost exclusively from the lowest ranks to high level management. Mirroring the social structure, firms are very hierarchical. Homegrown pharmaceuticals, like many other businesses in India, are often a mix of public and private enterprise. Although many of these companies are publicly owned, leadership passes from father to son and the founding family holds a majority share.

Indian pharmaceutical industry is growing at the faster rate. On the other hand, Indian pharma companies are looking for global business opportunities in the form of export business, contract research and clinical trials. Many Indian companies started realizing the importance of Intellectual Property Rights. The volume of money spent on R&D also growing to a greater extent. There are many challenges faced by the Indian pharma companies' right from their initial investment to strengthen their R&D and up to obtainment of Patent and other IP Protection for their new innovations. There are many legal formalities are to be carried out for drug discover

III. IMPORTANCE OF THE STUDY

Historically, India has neglected, and even made a farce of, pharmaceutical patents. In fact, it was not until 2005 that India offered patent protections for pharmaceutical companies at all. This has led to abuses of the compulsory licensing agreement with the WTO, and has led to major criticisms of other global pharmaceutical companies like Pfizer, Roche, and Bayer. According to these companies, India's generic drug manufacturing industry is destroying R&D funding and future innovation. This is because the companies which invented the brand name drugs are not receiving royalties; and therefore, losing out on profit, a lot of which would have been put back into R&D. While the WTO under the TRIPS agreement (Doha Declaration) has provided for the use of compulsory licenses (temporary patent rights for life-saving pharmaceuticals), recently India has been more lenient in its use of this stipulation. In fact, the first use was in 2012 for Nexavar. Since then India has used the compulsory licensing provision at least five times.

IV. SCOPE OF THE STUDY

This study has greater scope due to the increasing level of importance given by Indian Pharmaceutical companies in getting their IP Protection and numerous problems faced by them in every stage and the cost involved.

Tools and Techniques

- a) Garret Ranking Technique: This technique was used to rank the problems faced by . Pharma Industry in Intellectual Property Rights protection.

V. OBJECTIVES OF THE STUDY

The following objectives are formulated in order to make an in-depth analysis in to the study area.

1. To analyze the growth of Indian Pharmaceutical Industry in India.
2. To identify the challenges, issues and problems faced by the Indian Pharma Companies in IPR

Problems related to IPR in Indian Pharma Industry

Problems/Ranks	Ranks											
	I	II	III	IV	V	VI	VII	VIII	IX	X	XI	XII
Casual attitude towards disclosure of patentable drugs	18	8	5	6	7	5	4	3	2	3	2	1
Different legal system	15	7	7	6	7	5	4	1	4	1	2	3
Conflict and violation	3	4	2	1	5	4	7	6	7	15	7	1
Difficulty in prosecution of law breakers	7	6	5	4	5	6	3	2	3	2	18	1

Stop from using own traditional knowledge	5	3	6	2	4	3	16	2	5	7	6	3
Affects biological diversity and ecological balance	21	8	5	3	3	2	4	3	7	1	3	2
Heavy costs involved	6	7	4	5	3	2	6	5	17	2	3	2
Poor technology standards	20	7	5	4	3	3	3	1	7	4	2	3
Poor documentation	17	2	3	2	5	6	2	3	5	4	7	6
Difficulties in commercializing IP	7	4	5	1	2	4	3	14	7	6	5	4
Lack of IP related audit	24	6	5	3	3	5	3	2	2	3	4	2
Generics attack	5	4	2	1	5	4	7	6	7	13	5	3

3. Source: Primary data
4. There are totally twelve problems requested for ranking by the respondents and respective weights also assigned for each rank based on their importance. The same was listed below:
5. I Rank -12 Points
6. II Rank-11 Points
7. III Rank-10 Points
8. IV Rank-9 Points
9. V Rank- 8 Points
10. VI Rank- 7 Points
11. VII Rank-6 Points
12. VIII Rank-5 Points
13. IX Rank-4 Points
14. X Rank- 3 Points
15. XI Rank -2 Points and
16. XII Rank-1 Points
17. For each problem the concerned weight was multiplied with the ranking assigned. The total score for each problem was also calculated and subsequently mean score was also obtained. Final ranking for all problems are also obtained and listed in the following Table

Source: Primary data

Total and Mean Score of various problems related to IPR

Problems	Total Score	Mean Score	Rank
Casual attitude towards disclosure of patentable drugs	560	9.03	I
Different legal system	527	8.50	IV
Conflict and violation	337	5.44	XII
Difficulty in prosecution of law breakers	401	6.47	VIII
Stop from using own traditional knowledge	386	6.23	IX
Affects biological diversity and ecological balance	533	8.60	III
Heavy costs involved	415	6.69	VII
Poor technology standards	518	8.35	V

Poor documentation	435	7.02	VI
Difficulties in commercializing IP	379	6.11	X
Lack of IP related audit	545	8.79	II
Generics attack	353	5.69	XI

From the above table , it was found that out of twelve problems related to IPR In Indian pharmaceutical industry, Casual attitude towards disclosure of patentable drugs(9.03), Lack of IP related audit (8.79), Affects biological diversity and ecological balance (8.60), Different legal system (8.50), Poor technology standards (8.35) are the five most dominant problems faced by Indian Pharma companies. Poor documentation, Heavy costs involved, Difficulty in prosecution of law breakers, Stop from using own traditional knowledge, Difficulties in commercializing IP, Generics attack and Conflict & violation.

VI. FINDINGS

Out of twelve problems related to IPR In Indian pharmaceutical industry, Casual attitude towards disclosure of patentable drugs(9.03), Lack of IP related audit (8.79), Affects biological diversity and ecological balance (8.60), Different legal system (8.50), Poor technology standards (8.35) are the five most dominant problems faced by Indian Pharma companies. Poor documentation, Heavy costs involved, Difficulty in prosecution of law breakers, Stop from using own traditional knowledge, Difficulties in commercializing IP, Generics attack and Conflict & violation secured sixth, seventh, eighth, ninth, tenth, eleventh and twelfth ranking respectively.

Business growth Strategies (6.29), Increase in the International market coverage (6.19), Competitive Advantage (6.00), Opportunity for market expansion (5.92) and Ability to mobilize fund for expansion (4.77) are the core prospective areas in Indian Pharmaceutical industry for IPR. IP development (4.65), Chances for collaborations (3.84) and Increase in the value of the company (3.61) are least prospective areas for Indian pharmaceutical companies in IPR.

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Quality of Research and Development, Documentation formalities and Knowledge assets creation are the core areas in quality aspects in IP.

R&D Strategies (Mean score 3.95), Business Strategies (Mean score 3.73) and Advocacy (Mean score 3.58) are the core responses of Indian pharmaceutical companies towards IP Protection. Whereas Education and Incubation of Local Innovators and Negative Coping Strategies are ranked fourth and fifth positions respectively.

Availability of Low cost Technology, The growing role of emerging markets, the globalization of Technology, Technology Transfer and Foreign Direct Investment are the top five growth triggering factors in Indian pharmaceutical Industry.

VII. SUGGESTIONS

- The pharmaceutical sector serves a lot for the global sector and its part is very important. Thus investment on the research work of pharmaceutical field has to be increased to serve best to the global sector. The entire pharmaceutical market lacks in the global investment so enough funds are not raised for the medium and small scaled industries to do the research. There are only countable companies which are involved in the research of innovative molecules, which has to be increased.
- The current Scenario of R&D investment of Indian Pharma companies in comparison to the other global industry is low. So, the entire pharmaceutical market should do the global interaction to bring more and more investors in the sector so that the funds can be raised for the Novel Research work.
- Novel Drug delivery system are becoming part of emerging era of Indian medicine. The market is growing and has lots of potential in it. In coming 10 years, many new products are going to be launched which will account for raising global market of advanced targeted delivery products. Our Government must formulate a policy in keeping in the mind that long term planning will help the Indian pharmaceutical companies to grow faster and stronger.
- The period from discovery, synthesis to release a drug molecule in the market is about 10 to 15 years. During this period, companies have to do large investments and the returns are not confirmed as the molecule success is not predetermined. The returns in the critical antibiotic are not the same with the company invested in its research. Thus the period has to be reduces, as no much changes can be done in clinical and pre-clinical trials as they are compulsory. Only if the entire work is done by single domain then it can be done faster as compare to distributing it to different department. The period of process chemistry can be reduced by implementation of innovative techniques. Also the adoption of various electronic devices can help in shortening the clinical trial period especially reducing the time spent on data accumulation.
- Biomarker discovery is very promising for finding new relevant markers rapidly, without the details of mechanism of diseases thus saving time in the discovery process. As the use of inulin, which is used as marker led to discovery of creatinine. It's the major interest of pharmaceutical industry as biomarkers can solve various challenges in predicting diseases during the clinical trials by acting as intermediate markers.
- Biological system can be clearly understood by various computational system of cells, tissues and organisms. These systems are now being explored by pharmaceutical companies to maximize their chances in converting targets into therapies. Various computational methods are ligand based drug design, drug target docking, quantitative structure based design etcetera. Thus it would be son fully implemented with co-ordination of pharmaceutical industry and regulatory bodies.
- The new rule regarding the “product patent” had made a huge impact on growth of the pharmaceutical sector in India. Though the Patent System is important for Industrial Growth but it should be such that it should encourage the growth of the small scale industries. The number of patent filing lacks in Pharmaceutical and biotechnological industry as compared to other industries. As shown by the survey done by Entirely it is co-related that there should be enough funding so that small scale industries along with major player can involve in research work and so more patents can be filed.
- The best way is by exploring the work done by various post graduate students at college level. Industries can collaborate with the universities especially in developing country like India so that best potential can be explored and ideas can be commercialize. Various universities have come

up with University-Industry partnership cell so that company can explore best ideas of the young students. AICTE sponsored Partnership cell established at Manipal University, where student's projects are shared with the company experts.

- There should be special amendment in the patent law which can encourage small scale sector to participate in research. In developing countries like India, government along with association with the regulatory body should allow easy access to patents documents, which can be easily downloaded and their legal status can be accessed.
- Patents are the sign of development in research for a developing country. Hence every research work should be paid importance to convert it into reality which would serve the humanity.

VIII. CONCLUSION

It is obvious that management of IP and IPR is a multidimensional task and calls for many different actions and strategies which need to be aligned with national laws and international treaties and practices. It is no longer driven purely by a national perspective. IP and its associated rights are seriously influenced by the market needs, market response, cost involved in translating IP into commercial venture and so on. In other words, trade and commerce considerations are important in the management of IPR. Different forms of IPR demand different treatment, handling, planning, and strategies and engagement of persons with different domain knowledge such as science, engineering, medicines, law, finance, marketing, and economics. Each industry should evolve its own IP policies, management style, strategies, etc. depending on its area of specialty. Pharmaceutical industry currently has an evolving IP strategy. Since there exists the increased possibility that some IPR are invalid, antitrust law, therefore, needs to step in to ensure that invalid rights are not being unlawfully asserted to establish and maintain illegitimate, albeit limited, monopolies within the pharmaceutical industry. Still many things remain to be resolved in this context.

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