



Intellectual Property Rights Issues in Indian Pharmaceutical Industry

H. C. Bindusha^{1*}

¹*Sri Ramakrishna Engineering College, India.*

Author's contribution

The sole author designed, analyzed, interpreted and prepared the manuscript.

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ABSTRACT

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 World Trade Organisation, 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 World Trade Organisation under the Trade Related Aspects of Intellectual Property Rights (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. The total numbers of Indian Pharmaceutical Companies those who are having Research and Development facilities and also having Intellectual Property Rights for the past five years consecutively are take for this study.

Keywords: *Intellectual property rights; patent; research & development; clinical trials; copyrights; generic drugs etc.*

*Corresponding author: E-mail: bindusha.preeth@srec.ac.in;

1. INTRODUCTION

For a country like India, the sector that is likely to be affected strongly by an IPR regime, (more particularly with respect to product patenting), is the pharmaceutical industry. The impact may be felt either through direct competition or via patenting of Indian tropical bio-diversity by transnational companies. Therefore, an urgent need for policies and strategies to combat the situation. India has made significant strides in terms of self-reliance in pharmaceutical products. From being an importer of medicines in the first few decades after independence, today we are able to meet a good part of our essential requirement through indigenous production. Prices of indigenously manufactured drugs, once among the highest, are among the lowest in the world today. A net foreign exchange earner, with the annual turnover of Rs. 15,000 crores, the Indian pharmaceutical industry today ranks among the most developed in the third world, in terms of technology, quality and range of pharmaceuticals manufactured. The annual increase in the drug production is about 15% , while the average pre-tax profits for the industry is 8% of the annual sales. Nevertheless, the share of Indian pharmaceutical business in the present world market is only 1%, which suggests considerable opportunities for growth [1-4].

The reason for the low price of Indian drugs is twofold. First, as a result of a government intervention through the Drug Price Control Order (DPCO), the prices of all bulk drugs and thousands of formulations have been controlled so as to make them affordable to the common man. Secondly, and perhaps more significantly, many Indian companies particularly, during the early period of the industry's growth - have engaged in reverse engineering, a process that has allowed quick replication of new drugs at a low cost. But today with an impending strong IPR regime, the major issue facing the domestic industry is that of investing in R&D so as to better compete with international corporations in creating new drugs. The industry's R & D expenditure is currently about 2% of its annual turnover - considerably less than the 6-8% spent by many corporations in the western world. The cost of pharmaceutical R&D in the developed world is a steep one - around \$250-300 million per annum. In India, however, the expenditure might be only one third to one fourth of the last figure, primarily because of the low manpower costs.

It would thus appear that the imposition of a strong IPR regime is more an attempt by western countries and their pharmaceutical corporations to consolidate the gains they have made in the last several decades. Just when Indian pharmaceutical companies are beginning to acquire strength under the process patent regime they are being forced to concede the gains to transnational. Of course, this need not imply that the Indian sector should be provided a completely protectionist environment indefinitely; rather there should be a time frame arrived after due consultations with the industry. Presently our timeframes are dictated by the external environment and therefore does not do justice to our internal concerns. Some of the adverse changes that could affect the Indian pharmaceutical industry under the IPR regime are: increased R&D expenditure and hence higher Indian drug prices, and lower export of drugs because of the inability to use process patents. Overall, however, the use of IPR will not be an unmitigated disaster if the industry invests well in basic research, new product launches, a thrust into global generics market and licensing-in of products from companies that do not have a presence in India. There needs to be rapid development of innovative, non-infringing processes for products going off-patent internationally and a leveraging of the low cost domestic manufacturing. In an ironic sense, India has already benefited from an impending IPR regime [5,6].

For, with the recent attempts by western players at patenting age-old Indian botanicals such as neem, turmeric, jar amla and several others, Indian policy makers have suddenly woken up to the advantages of patenting our bio-diversity [7].

The patent owner has only three months to conduct discovery; prepare its own expert declarations; prepare its claim construction positions; demonstrate why the cited patents or printed publications do not qualify as prior art; and present arguments why the claims are patentable in view of the prior art. The Patent and Trade Mark Office(PTO) is also particularly reliant on experts, making their selection all the more important. If due diligence reveals a problem with one or more patent claims, the patent owner should consider addressing the problem early. Options may include pursuing the appropriate protection in a continuation application or corrective action in an ex parte The Patent and Trade Mark Office(PTO) proceeding

such as reissue, post-grant correction or supplemental examination.

In addition to allowing the patent owner to address possible problems without the involvement of an adverse party, the patent owner likely will have more flexibility in amending claims ex parte given that amendments have been rarely allowed in IPR proceedings. By addressing potential problems in a continuation or an ex parte proceeding, pharma can potentially pre-empt the damage of an adversarial IPR attack.

There are many problems faced by the Indian Pharmaceutical companies in terms of creating the base for IP research as well as legally protecting them. In addition to this, there is a need for regular search also to be initiated to monitor the entire World to avoid duplication or breach of any rights owned by us. The researcher has identified totally twelve problems faced by the Indian pharmaceutical companies related to their Intellectual Property protection. They are listed below:

a) Casual attitude towards disclosure of patentable drugs

Many pharmaceutical companies are facing this problem very frequently. Because maintaining the secrecy is very important in protecting your innovative ideas along with materialization in terms of product outcome. Employees are also taking these type of important things lightly and having their loose take not only within the company but also with outsiders. It leads to lot of complications and problems particularly others may utilise such kind of information for their own advantage [8,9].

b) Different legal system

We don't have any common law for Intellectual Property Rights World wide. But all countries are having their own laws for protecting the various rights associated with IP. Understanding them is difficult for a common man. Filing a case of facing the case based on such regulations are also very tough now a days.

c) Conflict and violation

Another peculiar issue involved with pharma IP is conflicts and violation of rights. It is very difficult to monitor and scrutinize the happenings of Worldwide particularly related to our own patented drug. Identifying the violation and set right such issues are also more complicated and to do the corrective orders too.

d) Difficulty in prosecution of law breakers

Since International laws related to Intellectual Property are huge. If any suit is made by us or any suit filed on us will result in complications. Likewise, any person or firm of company is breaching such laws; it is difficult to bring them to the law preview and proving the damage with all supportive evidence.

e) Affects biological diversity and ecological balance

Since heavy research work involved in inventing the drug and also in manufacturing such drugs, it is directly or indirectly going to affect the environment. That is affecting biological diversity and ecological balance. This also considered as core issue.

f) Heavy costs involved

Scientific research itself involves heavy initial investment and also considerable recurring expenses too. In addition, the documentation of scientific outcome of the research also involved huge monetary commitments. It is essential to understand the degree of problems resulting in terms of operational expenses as well as capital expenditure.

g) Stop from using own traditional knowledge

Traditional knowledge is the great strength for our country. But when you go for patented drugs and other intellectual property rights, it may crush the touch of traditional knowledge and people may ignore the importance of such valuable knowledge. It may slowly go on the darker side.

h) Poor technology standards

Though we went for liberalization, Globalization still we are at infant stage in many technological up gradation and inventions. Many companies are using good old machineries for production and old lab setup for Research and Development. The outcome also will be poor from such facilities.

i) Poor documentation

Documentation of each and every step involved in the process of drug invention is also equally important to get the IP protection for the same. But in reality, many Indian pharmaceutical companies are not good in doing proper documentation for the invention and other allied inputs in drug discovery. This will pull the viability

of getting patent or delay the process. Sometime may lead to give competitors to get the same kind of IP protection. So, time value is very important for all documentation.

j) Difficulties in commercializing IP

Between an inventor's "Aha!" moment and his financial reward are the challenges of commercialization. It is a rare inventor who does not encounter difficulty in funding, manufacturing, distributing and marketing his invention. The fruits of research may yield an intriguing invention, but entering the market often proves equally challenging. Many factors complicate the journey to commercialization: Undue delay caused by the inventor's attempts to "perfect" his or her product may allow a competitive, lesser quality product to enter the market, to the detriment of the inventor.

- Licensing manufacturing to another may hasten market entry, but at the expense of the inventor's control.
- Funding may be exhausted in pre-sales activities.
- Distribution and supply chains take time and expertise to establish.

The pharma inventor who finds equal pleasure in inventing and reaching market is rare. But the successful inventor must proactively attack these practical problems of commercialization. Many

Indian pharmaceutical companies are facing the problem of commercializing their inventions.

k) Lack of IP related audit

More than a decade after state auditors recommended ways that the state could make money from its intellectual property, only a handful of agencies have implemented policies for managing their copyrights, trademarks, patents and trade secrets in Indian Pharmaceutical companies. Our Indian pharmaceutical units are not having the proper setup to carryout IP audit in their organization to monitor the happenings and to do measures to document every technical movement.

l) Generics attack

Generics' IPR challenges are a real and growing threat to pharma patent holders. By starting its defense early--indeed during the drafting and prosecution of the application--pharma patents can be built stronger to better defend these IPR attacks. Proactively marshalling evidence, engaging experts, and working with IPR-experienced counsel to develop a defense, even before any IPR petition is filed, also may be crucial. Indeed, generics' IPR challenges can come at almost any time and, once filed, they proceed at a fast pace. India is a country where many pharmaceutical companies including market leaders are actively involved in generic drug manufacturing. It is giving tough competition and attracting more customers due to price conscious attitude [10].

Table 1. Problems related to IPR in Indian pharmaceutical 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

Source: Primary data

Table 2. 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

Source: Primary data

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.

2. CONCLUSION

- 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.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Author has declared that no competing interests exist.

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