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SCOPE OF PHARMACEUTICAL IPR IN INDIA AS A CAREER PERSPECTIVE

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ABSTRACT

Pharma Industry is one of the giant industry having huge profits, knowledge driven and growth in India because of government policies and limited competition from overseas during the past three decades. In Pharma industry from literature search till the final stage of product launch there were lots of hardships faced in terms of production, initiation etc. The project may succeed or may not incurring losses to the company and the team. If they succeed because of increase in competitiveness, economic dominance in the global markets claiming a method, product, process etc. became a mandatory issue. Pricing of the medicine, development, marketing of a new pharmaceutical product across different parts of the globe is possible by protecting the intellectual property rights of the invention. IPR plays a key role in launching a drug at equal pricing at different parts of the globe, the unequal pricing of a drug in different countries results in Pharmaceutical controversies between the developing countries. All the developing countries in the world have strong patent system to preserve the novelty of the invention. Indian Pharma industry is utilizing this opportunity to spread across the globe by commercializing IP protected Pharmaceutical products on exclusive or non exclusive basis with one or more companies. The Indian pharmaceutical industry is a successful and having a consistent growth from the past three decades in terms of high technology driven inventions. Indian pharmaceutical industry is entering into international markets from domestic markets for earning huge profits. In this context the field of IPR is producing more jobs to the young generation who wish to enter the top companies involved in R&D activities.

KEYWORD: Pharma Industry is one involved in R&D activities.

INTRODUCTION

Governor General In Council in British India applied the laws passed by the British Parliament such as (a)Patents And Design Protection Act 1872, (b)Protection of Inventions Act 1883 which were consolidated into Inventions and Designs Act 1888. The first comprehensive Indian legislation for Patent and Deign was enacted in 1911. This enabled the British to keep the goods of other European Nations from entering the Indian market. After India become independent, two important Committees were constituted to consider reforms to Indian Patent law. 1. Justice Bakshi Tekchand Committee. (1948. Retired Judge High Court of Lahore) 2. Justice Rajagopala Iyengar Committee. (1959) Retired Judge Supreme Court. The Indian and international pharmaceutical industry witnessed a change after the formation of the World Trade Organization (WTO) in 1995. India adopted Trade related aspects of intellectual property rights (TRIPS) agreement. Indian pharmaceutical company is 126years old since it started its first production of modern medicine by adopting modern techniques 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. The pharmaceutical companies especially MNCS marketed their drugs by importing them from their home countries and making formulations in India to gain huge profits. The Indian companies lack proper awareness during those days for applying for the Drug master file and patenting of their pharmaceutical products. The MNC companies patented their pharmaceutical products before publication to gain exclusive rights to manufacture the pharmaceutical product which resulted in restricting the Indian pharmaceutical companies to manufacture the product during the validity of the patent of the patentee. The dominance of the MNC companies increased during those days which resulted in over pricing of the drug product and 80% market share was occupied by the MNC companies. Situation changed over time after 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. Reddys laboratories, Glennmark, Ranbaxy who prospered under the patent regime further realized the importance of filing international patents and increased their revenues by marketing their patented products in the international markets. 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.

KEYWORDS: Pharmaceutical industry, TRIPS, Product patent, R&D, IPR department, Job growth.

Objective of the study: The basic Objective behind this study is to analyse the growth in filing of pharmaceutical patents and its effect on the Pharmaceutical IPR job market.

Research Methodology: Qualitative analysis is derived from this study which ensures that research is conducted more effectively and efficiently. All the data collected during the study were from the authenticated organizations and from the available literatures.

Pharmaceutical Patents: Though the mandate of the TRIPS Agreement requires patents to be made available for any invention in all fields of technology, patent laws throughout the world recognise patents for pharmaceuticals as a special branch which raises issues not common to other fields of technology. As pharmaceuticals being part of public health they are considered inevitably, leading many countries around the globe. Provisions under the Patents Act 1970, the patentability of pharmaceutical and chemical inventions are contained in section 3 of the patents Act, the relevant clauses are reproduced below:

What are not inventions.- The following are not inventions within the meaning of this act,

*The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a new substance or of mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation

For the purposes of this clause, salts, esters ethers, polymorphs, metabolites, pure forms, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy. Clauses of section 3 (e) (I) sections 4 will have some guidelines regarding the said topic. Whereas Article 27 of the TRIPS agreement discusses about the patentability of the inventions within their territory for prevention of the commercial exploitation.

Section 3(d) and its Importance on Innovation: Section 3 (d) also may be viewed as an exception under the ambit of art 27.2. Article 27.2 of the TRIPS Agreement provides for exceptions to patentability made on the ground of public health. The said provision gives enough room for the member countries to carve out exceptions on the ground of public health. Such measure may also extend to pharmaceuticals as patents for pharmaceuticals can have a direct impact on human health The Doha declaration on public health further reiterates that the provision of the TRIPS agreement must be interpreted and implemented in a manner supportive of WTO members right to protect public health and to promote access to medicines to all. The impact of such a provision on pharmaceuticals can certainly be viewed as a measure to protect public health and promote access to medicines. Section 3 (d) comprises three parts and one explanation. The section states that the following are not inventions within the meaning of the patents act:

(1) The mere discovery of a new form of a known substance which does not result in the known efficacy of that substance: or

(2) The mere discovery

(1) Of any new property or new use for a known substance: or

(2) Of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

(3) New product by a known process.

Existence of IPR department in the company

In pharmaceutical industries especially involved in the R&D activities it has became a mandate to have an IPR department in their company to adhere to TRIPS requirements. This doesn't mean that all the companies have devoted their resources for basic R&D. Very less companies have IPR department before 1995 and it is a transitional phase from 1995to2018 that each and every company involving in R&D activities now a days have their own IPR department which resulted in increase of demand for human work force to work in this field. Rising in the revenues generated by these companies from commercializing their patents on exclusive and non exclusive basis resulted in increase in their revenues which further decides the fate of the company and a guaranteed long term benefit of 20yrs from the claimed patent.

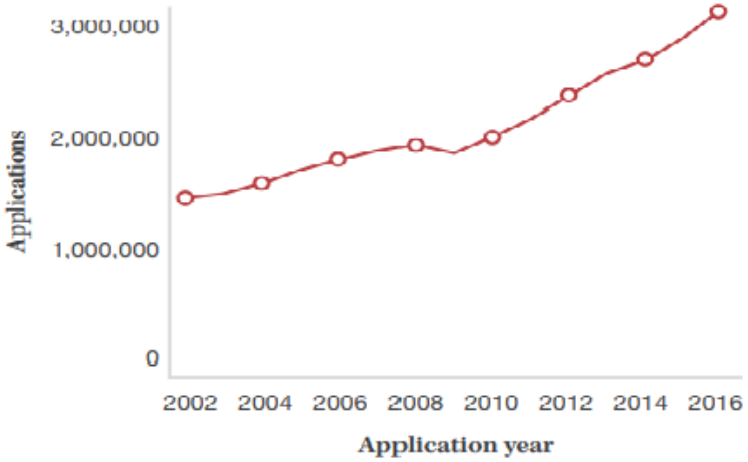
Pharmaceutical Industry and Institute Collaboration in India

One of the critical factors in building innovation ecosystem and for Drug Discovery is Academia-Industry linkage. In global markets it is necessary for India to innovate and

promote creativity which needs to protect the IP created out of the public funded research and development activities taking place in governmental institutions like IIT, IISC, ICT, NIPER etc in which Government had invested large funds. The proposed Protection and Utilization of Public funded IP Bill, imposes obligations & creates rights to optimize the potential of public funded R&D & it provides incentive to create IP and mechanism for its protection and utilization. The above bill encourages innovation in small and medium enterprises, promotes collaboration between Government, private enterprises and non-Government organizations & commercialization of IP created out of public funded R&D and the culture of innovation in the country. At present, government funded Universities & autonomous research Institutions cannot commercialize the fruits of their research. However, after the approval of above bill by the Government would alter the existing IP rules by allowing academic institutions, rather than the government, to patent publicly funded research and would reward institutions and inventors with a share of the royalties i.e. around 30% and licensing fees generated from the commercial products to the inventor and commercialization of the invention. This bill will enhance awareness of IP in universities, academic and research institutions. It will also increase the responsibility of universities, academic and research institutions to encourage students, faculty and scientists to innovate. Such innovations can be utilized for raising financial resources of these establishments, through royalties or income. The income from IP will promote self-reliance and will minimize dependence of universities, academic and research institutions and other recipient organizations for Government funding. This bill would allow government funded academic institutions to patent their inventions & it should result in greater interaction between Industry, Academia and Government. There is a need for increase industries to collaborate at large scale with academic institutions in near future to increase the potentiality of the filed patents and to train their workforce in a suitable manner.

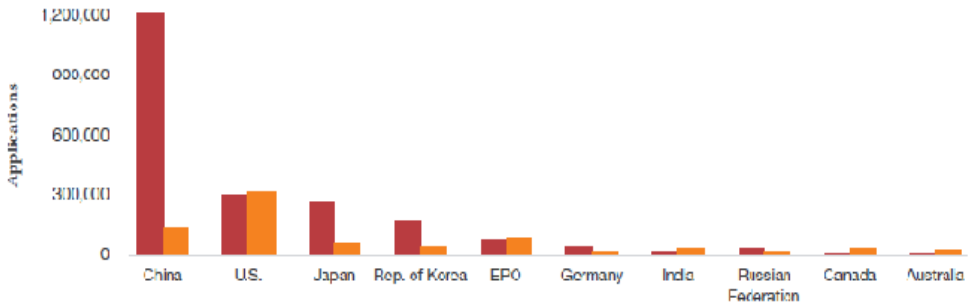
Academicians should leave their comfort zone of pure teaching. The restrictive internal policy of the academicians is hindering innovation in their particular field. Academia is largely unaware of the real industrial and national needs and unable to market its strengths to industry adequately. Other inhibiting factors are lack of appropriate incentive to faculty and specialized technical infrastructure (R&D Lab.), absence of proper recognition for practicing faculty as compared with pure academics worshipper, bureaucratic hiccups in utilization of consultancy funds, absence of exclusive university-industry interaction cell in campus, etc.

Patent applications Worldwide: For the first time, more than 3 million patent applications were filed worldwide in a single year, up 8.3% from 2015 (figure 1). Driving such strong growth was an exceptional number of filings in China, which received about 236,600 or 98% of the additional filings. The next largest contributor was the United States of America (U.S.) with around 16,200 additional filings. Following a modest increase of 4.5% in 2014, the growth rate picked up in both 2015 (+7.7%) and 2016 (+8.3%), aligning with the annual growth rates of between 8% and 9% observed between 2011 and 2013. But when patent applications in China are excluded, applications filed in the rest of the world grew by only 0.2% in 2016.



Source: Standard figure A1.

Figure 2
Patent applications at the top 10 offices, 2016



Source: Standard figure A8.

Initiatives from Govt of India

Under Make in India several initiatives are laid down to increase the scope of manufacturing of Indian pharmaceutical products. India is one of the largest producers of pharmaceutical

products and a leading player in the global generics market, exporting nearly 50% of its production. The turnover of Indian pharmaceutical industry was estimated at INR 2,04,627.1 crore in FY 2015-16. The Indian pharmaceutical industry has witnessed a robust growth in recent years growing from INR 177,734 crore in FY 2014-15 to INR 204,627 crore in FY 2015-16, registering a growth of 29% as compared to the growth of 12% from INR 158,671 crore during FY 2013-14. In FY 2015-16, the exports of Drugs, Pharmaceuticals and Fine Chemicals was INR 1,06,212.4 crore. In the generics market, India exports 20% of global generics, making it the largest provider of generic medicines globally.

FDI Policy

- 100% FDI has been allowed through automatic route for Greenfield pharmaceuticals projects.
- For Brownfield pharmaceuticals projects, FDI has been allowed up to 74% through automatic route and beyond that through government approval.

The Drugs and Pharmaceuticals industry has witnessed USD 2.93 billion equity inflows during April 2014 to December 2016.

Cluster Development Program for Pharma Sector (CDP-PS)

Launched on June 17, 2015, the scheme is being implemented on a Public Private Partnership format through a one time grant-in-aid, which will be released in phases for creation of Common Facility Centers (CFC).

Infrastructure Development Indian Drugs and Pharmaceuticals Limited (IDPL), a Central Public Sector Enterprise under Department of Pharmaceuticals, has modernized the tablet manufacturing section of its Gurgaon Plant, which was commissioned with an investment of INR 3 crore. This has enabled the PSU to mass manufacture new products in the field of diabetes, oncology, nephrology and cardiology at affordable prices.

Skill Development

To keep pace with the growing demand for highly skilled R&D professionals the following skill development initiatives have been undertaken:

1. Transformation of National Institutes of Pharmaceutical Education & Research (NIPERS) as Innovation hubs

2. 11 NIPERs were approved till 2015. 3 new NIPERs at Chatisgarh, Maharashtra and Rajasthan were announced in Budget 2016-17.
3. In 2015-16, INR 95.63 crore was disbursed for NIPERs. AICTE issued an Advisory on honoring NIPER Degrees by all AICTE Institutions.

Limitations of the Study

Based on the information available through trusted sources the above work has been carried out and cannot be considered as a final study. Proper references were cited and we would like to thank each and everyone who helped us during the study. This is an indicative study on the scope of pharmaceutical IPR on job markets and cannot be constructed as a conclusive study.

CONCLUSION

It is evident that based on the above statistics, investment is flooding into the pharmaceutical industries. There is a vast scope for Pharmaceutical IPR to be chosen as a career option for future generations. Govt of India had taken up several initiatives to make India a knowledge and technology hub for future generations. Indian scientists are capable to develop and to protect their Intellectual Property. Increased awareness about patents had helped companies to file in lucrative markets.

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