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Introduction
INTRODUCTION

Indian pharmaceutical industry is one of the most vibrant knowledge driven industries in India. It has witnessed spectacular growth with significant advancement in domestic technological capabilities over the past three decades. The industry produces almost entire range of therapeutic products and is capable of producing raw materials for manufacturing a wide range of bulk drugs. Currently over 90% of the modern medicines consumed in India are produced locally (Nakra et al., 2010). When India attained independence, the pharmaceutical industry was of modest size with a total market of about US $28.5 million. In post-independence era, India’s economic planner included the pharmaceutical industry in core sector of economy that emphasized industrialization and achievement of self-reliance in a bid to free itself from dependence on multinational corporations (MNCs). Currently, the pharmaceutical industry in India is estimated to be approximately US $8-9 billion industry, growing at a rate of about 10% annually (Sreedhar et al., 2011). It is ranked 3rd largest in the world in terms of production volume (accounted for 8% of global output in terms of volume) and 14th in terms of value in 2010 (Kallummal and Bugalya, 2012). It was estimated to produce between 20-22% of world’s generic drugs (in value terms) and offer 60000 finished medicines and 400 bulk drugs used in formulations (Rai, 2008). Thus, the industry that was almost non-existent at the dawn of independence is now a global competitor. Due to such fast growth of low-cost domestic producers of drugs, the market shares of the multinational companies in Indian market declined from 75% in 1971 to 27.2% in 2003 (Nauriyal, 2006). The main factor responsible for this transformation of pharmaceutical industry was a host of strategic government policies aimed at promoting indigenous technology and production. Starting public sector companies to assume a leading role in enhancing local capabilities in bulk drug production, adoption of process patent regime, and regulating activities of foreign firms were the important policy initiatives (Pradhan, 2007).

The Indian pharmaceutical industry has been characterized as “long tailed’ i.e. there are a small number of large firms and large number of small firms (GOI Annual Report, 1999-2000). Pharma small and medium enterprises (SMEs) in India are essentially a fragmented and heterogeneous sector having varied levels of technological capability.
These enterprises have played a crucial role in boosting the overall growth of Indian pharmaceutical sector. Small and medium enterprises (SMEs) account for 87% in production by volume and 40% by value in the pharma industry (OPPI, 2012; Chauhan, 2012). Pharma SMEs are cost-effective resource of knowledge, skill and employment. These small firms are producers of technology intensive bulk drugs and have contributed in enhancing indigenous capability in the sector (Jinoy, 2010). They also provide the accessible essential drugs to the country and play an important role in the economic and social development of the country by discovering, developing, manufacturing and providing medicines to the vast population of our country and forming an essential part of the supply chain for the larger sector (Sehgal, 2009). Like their large domestic counterparts, SMEs have grown around a soft patent regime that India adopted in early 1970s. Under the process patent regime, these firms have effectively utilized the technological imitation, reverse engineering and process development as a means of advancing their competitive capabilities in specific areas.

1.1 Trade Related Aspects of Intellectual Property Rights (TRIPs), New Patent Regime and Challenges for Indian Pharma SMEs

After India gained independence in 1947, it still followed the old British law. During this period after independence, 80% of the pharmaceutical industries in India were controlled by foreign multinational pharmaceutical companies, which owned 80-90% of the patents (Kiran and Mishra, 2011). During this period prices of drugs were extremely high and this concerned the government of independent India. To identify the reasons for the high prices of medicines and recommend solutions, the government commissioned two national level committees. The first post-independence amendment of the Indian patent law was promulgated in 1950 after the recommendation made by the first committee, the Tek Chand Committee (Mukherjee, 2006). The prices of drugs were still high and this led to second national committee known as Ayyangar Committee (Ayyangar, 1959). Based on its recommendations, the Patent Bill of 1965 was placed before the Parliament and later passed as Indian Patent Act 1970. The Patent Act 1970 ended ‘product’ patent protection laws left over from the British colonial era and recognized the patent on processes (Kumar and Pradhan, 2003). The objective of the Act was to foster development of an indigenous Indian pharmaceutical industry and to guarantee access to low-cost drugs to the Indian public. The act enabled the Indian
companies to legally produce drugs patented elsewhere through reverse engineering processes without paying the license fee and selling the world’s best selling patented drugs in India at cheap and competitive rates (Rai, 2008). This patent law helped India transform from a country having one of the highest drug prices to having the lowest ones (Gerster, 2001). In a period of 25 years, capital investment in the Indian pharmaceutical industry increased from Rs 225 crores to Rs 2,500 crores and investment in research and development (R&D) increased from Rs 10.50 crores to Rs 320 crores, which enabled India to become a major player in the pharmaceutical sector internationally (Mukherjee, 2006).

The negative impact of Indian Patent Act 1970 was that too many small and medium scale industries entered the pharma sector as there were no intellectual barriers. India joined the World Trade Organization (WTO) in 1995 and automatically became a signatory of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) in 1995. The TRIPs Agreement provided a transition period till 1st January, 2005 for developing countries like India to implement the agreement and to introduce product patent regime in pharmaceuticals, food and chemicals. Under the TRIPs Agreement, India has amended its patent law in 2005, abolishing its ‘process’ patent law and reintroduced product patents for pharma, food and chemicals (Nair, 2008). With the end of transition period in January 2005, the pharmaceutical companies have obtained full patent protection on their products in major markets in developing countries such as India and prevent local firms from manufacturing generic copies of their patented products on the basis of reverse- engineering (Chadha, 2005).

Indian pharmaceutical firms responded to liberalization in different ways. Many large-scale pharma industries viewed patent system with positive attitude. They understood that staying ahead in the evolving competitive scenario will require well focused R&D activities, translating innovations faster to viable technologies or products, ensuring their protection through IPRs, quality manufacturing and reaching the market first (Chaturvedi, 2005). The adoption of product patent regime in 2005 gave a very tough time to small and medium enterprises and generic companies to survive in this competitive market that had earlier survived on generic drugs or by making some drugs which were in high demand, protected by process patent in India and manufacturing them by alternate processes (Janodia et al., 2007). Since small firms are often
constrained by their size limitations in sales, investment or employment in R&D sector with limited financial resources, meeting emerging high end challenges was not as smooth as in case of large enterprises.

1.2 Barriers and Limitations of SMEs in Promoting Innovations

The need of innovation applies to all sizes of business and a great deal of attention is being paid to the rising challenges presented due to globalization especially by countries such as China, Korea, Japan and Brazil. However, SMEs face particular problem because of small size of their operations and they rarely have the resources to address the issues without any aid. Infrastructure inadequacy, insufficient resources for investment in research and development, lack of institutional support, industry regulations as well as price controls, taxes and duties were perceived as major constraints as well as hindrances to the growth of pharma SMEs. Few companies also expressed apprehensions regarding the threat from spurious and counterfeits available in the market (Dun and Bradstreet, 2006). There is a perennial problem of insufficient funds for acquiring advanced technology to enhance production, quality and lower cost thus SMEs have marginal or no access to the state of art technologies. SMEs undertake limited R&D efforts. As a result, innovations by SME pharma units mainly comprises of minor adaptations to existing generic products, innovations in design, management and marketing practices. In many SME units, innovations are of informal nature, without formal R&D investment, R&D labs or R&D personnel, which ultimately affects the ability of SMEs to offer innovative solutions. SMEs can’t compete with large firms in attracting sufficient number of highly qualified workers and experts thus that lead to limited resources available for economically and technologically effective innovations. They have real or perceived quality problems and there is inadequate adoption of good manufacturing practices (GMP) by SMEs to meet global quality (Nair, 2006). The adoption of information technology (IT) techniques in production and processes are also limited (Jinoy, 2010). The main barrier faced by SMEs is the limited knowledge of the ins and outs of the intellectual property rights (IPR) system. There is a lack of clarity about the relevance of intellectual property rights to their business strategy and competitiveness (Nair, 2006). They have poor IP management skills and thus, find the system too complex and expensive to use.

However, SMEs are long acknowledged as innovation and growth engine and naturally have a key role to play in developing a country’s technological edge. As R&D is both costly and risky, SMEs undertaking R&D quickly face financial constraints that hamper
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the development of their innovative projects (Rassenfosse, 2012). Jones and Jain have also emphasized that developing and investing in the new technologies can be beneficial for the SMEs but it is a challenging task for SMEs because they have reduced access to the technological information and to the financial and personnel support needed for technological research and development (Jones and Jain, 2002). Unlike large scale pharmaceutical industries, SMEs have limited resources and are relatively unable to absorb the cost and risk associated with in-house technology development; small business managers are most often unable to free themselves or their employees from part of their duties to search for viable new technologies (Eden et al., 1997). The focus of SMEs is limited on very specific specialized set of needs. They are concerned principally with the market rather than with the idea. SMEs view of the world is quite different from the linear model or ‘triple helix’ model. Woolgar et al. (1998) observed that in SMEs centric universe (Figure 1.1), SMEs seem to relate most closely and intensively with their suppliers and customers and to slightly lesser extent with their competitors. They have connections with trade press and trade exhibitions etc.

![Figure 1.1: The SME- centric universe (Reproduced from Woolgar et al., 1998)](image)

It was also observed that they lack the institutional support and communicate less frequently with colleges, graduates from the universities etc. In general, government and universities fall well outside their focus of attention.
1.3 Benefits of Innovative R&D for Strengthening Pharma SMEs

Surveys have found that small firms are less likely than larger firms to undertake R&D activities (Pradhan, 2003). This is true even when they have great potential to lead to improved productivity and the production of new and value added pharmaceutical products. Research and development enables a company to stay competitive and build customer’s reality. The product developed can help an industry to boost sales, increase profitability, enhance the brand and gain reputation as an innovative business house to open new markets, attract the best employee through enhanced reputation, find new business partnerships and attract external finance.

As mentioned under TRIPs, strengthening of IPR protection system affects SMEs. The fall out is that SMEs are largely unable to exploit the protected and exclusive products discovered and developed by large R&D based corporations and their licenses. The companies operating in the pharma sector have to rely on new technologies for improving their efficiency and enhancing their commercial viability (Nair, 2006). Econometric studies have also mentioned that the key drivers of growth in pharmaceutical industry are innovations which create new therapeutic areas and markets and incremental therapeutic improvements which increase the competition in the existing markets (Bottazzi et al., 2001). But developing a new technology drains both commercial and natural resources, which can be avoided by using IPRs and transfer of technology mechanisms. For all these reasons, SMEs need assistance in gaining access to information about new technologies and effectively using the information obtained.

1.4 An Innovative Approach for Promoting Innovations in Pharma SMEs through Intellectual Property (IP) Integration

SMEs are facing many challenges related to globalization of the Indian economy followed by introduction of TRIPs Agreement in multilateral trade agreement which has resulted in a situation of international and internal competition for the SMEs in India. In order to fulfill the regulatory and social needs for improved quality of the medicines and conformance to more stringent standards, innovative and collaborative approaches are of utmost importance. These industries can stabilize and survive if they are able to generate innovative processes and products to meet the market demands. It is at this
point, that management of knowledge and intellectual property become extremely crucial for SMEs in this era of globalization.

Intellectual property protection and establishment of workable technology transfer mechanisms are the next important steps in making SMEs globally competitive. SMEs that engage in technology transfer process are able to benefit from R&D conducted by external organizations or subsidiaries while avoiding exposure to the cost and risk associated with the in-house development. While for large companies, the financial wealth of the company could be from intangible assets, even for SMEs a significant patent or trademark can add considerable value to its assets. However, lack of awareness and experience of these mechanisms is a major bottleneck that prevents pharma SMEs from exploiting the benefits of IPRs (Bansal, 2006a). Intellectual property rights are powerful tools, which can greatly benefit SMEs by giving access to latest improvements/technologies not only for the new but existing processes through patent literature. IP databases help industry quickly identify relevant national or global partners whether in industry or academic institutes thus IPRs act as a bridge between knowledge creators and knowledge users. Industry can generate revenues through licensing out of its own IPRs, if any. Recent IP trends also help industry to know the global movement of technology in an accurate and precise manner.

In fact, these mechanisms promote commercialization of technology generated in universities or R&D labs. Technology transfer promotes innovations - it leads to better processes, better products and promotes new technologies and economic development (Cohen, 2004). Further, the investment in R&D can only be meaningful if the products or processes developed by these institutions are actually adapted and utilized by industries including small-scale industries. As SMEs operate in a very competitive world, they have to be creative, innovative and require a continuous improvement in their existing technologies and operations. The primary purpose of technology transfer, thus, is to reduce the R&D cost; speed up the product development and to gain new technologies from appropriate partners (Rouach, 2003). Technology transfer provides opportunities for exchange of information and materials with industry and also generates income for reinvestment into research and teaching. Duplication of R&D efforts in developing a new technology drains both commercial and natural resources which can be avoided by in-licensing the required technology which is already available.
or developing the same in collaboration with academia, which has highly trained and qualified manpower and also vast research infrastructure developed over the years. On the other side, academic and research institutes also engage in technology transfer for recognition of achievements, attraction of corporate research support, licensing revenue to support further research and education and regional economic development. The ultimate benefits of technology transfer, however, are the public benefits derived from the better products that reach the market and the jobs that result from the development and the sale of the products.

In order to promote technology transfer activities, few institutional links have been fashioned to bridge the world of science and technology with the world of trade and market. However, the ‘islands’ or gaps of academic research have been found to coexist with the ‘islands’ of industrial activity (EIMS, 1995). The reason behind the existence of these ‘islands’ is not clear as it can be the fault of knowledge creators or the knowledge users, or of prevailing economic regime. Literature reveals that such islands rarely exist in case of bridging of universities and large-scale industries as evident from various successful case studies (Campbell et al., 2004).

Figure 1.2: Bridging the ‘Islands’ or the gaps through university-industry interactions

Large-scale industries are generally self-sufficient in their research and development requirements. They frequently have large and well-equipped research departments. Many also outsource their R&D or keep an eye on research scene looking for new developments of potential benefits. The relationship of universities or research institutes with large firms in research-intensive sector stands in sharp contrast to those with SMEs in traditional areas of industrial activity. On the other hand, pharma SMEs are less self-
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sufficient and they are less likely than larger firms to undertake R&D activities. SMEs have a significant role in the national economy in terms of their sizeable contribution to GDP, employment generation, export performance and achieving sustainable national economic development (WIPO, 2003). SMEs basically require new technologies that can provide increased productivity, efficiency, improved product quality and reduced wastage, long run cost-savings, enhanced performance and competitive capabilities.

Small-scale industries do not have their own R&D because they are mainly production oriented and can not afford to engage in monetary or human resources required for R&D. On the other hand, academic institutes are rich in highly qualified human resources as well as R&D infrastructure but lack of actual product manufacturing facilities at pilot or industrial scale. Academia-industry interaction brings these two groups together for the benefit and the welfare of the society. The industry benefits from the vast experience and resources of academic institutes for solving their problems in a very cost effective manner through consultancy and technical guidance. For academic institutes, the benefit of such linkages lies in resource generation for research institutes, which can fund laboratory infrastructure, provide scholarships for students and also promote innovation and creativity to solve the problems brought by the industry. Further, they can validate their output at industrial scale and generate revenues.

In view of the above facts about the present scenario of innovative developments in the pharma SME sector in India, the present study has been undertaken to explore the ways and means of exploiting the research carried out in the academia using public funds for benefit of the pharma SMEs in terms of enhancing their global competitiveness and also capacity to bring about innovative and improved products. In addition, it was proposed to investigate whether problems of the industry could be addressed in a practical, low cost and effective manner by using innovations embedded in free domain intellectual property rights and effective technology transfer as ‘tools’ by taking small and medium industries as partners in this endeavor. It is a known fact that small industries are more open, easier to approach and are in a position to take quick decisions than large industries. Small or incremental innovations matter a lot for SMEs unlike bigger corporates, where the operations are stable and change is difficult to bring about. Hence, in the present work, an attempt was made to improve the SMEs output and quality by
integrating free domain IPRs into existing pharma SMEs processes by bridging the gaps through R&D output from academia and various benefits arising from such an effort. The major objectives of the study were:

1) Current status of small and medium pharmaceutical industries with respect to IPRs after implementation of TRIPs agreement.

2) Identification of small and medium pharma units, which have necessary capacity for integration of Intellectual property rights and technology transfer mechanisms.

3) Identification of thrust areas wherein the products or processes can be improved in the identified pharma SMEs.

4) Identification of public domain inventions (IP) that can be used for improvement of identified products/ processes in the selected SMEs.

5) Identification of R&D gaps between selected public domain inventions (IP) for implementation in selected SME products or processes.

6) R&D work at university laboratory to bridge the identified gaps for implementation in selected industries.

7) Practical integration of intellectual property rights and technology transfer mechanisms at industry level.

8) Analysis of benefits arising from this mechanism to pharma SMEs.