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2.1 Evolution of Indian Pharmaceutical Industry

Before independence, India was fully dependent on other nations for vital drug supplies as the technology for the production of essential drugs was not available to India. At the time of independence, the Patent and Design Act 1911 provided product patents for all the inventions, including foreign inventions, for a period of 16 years from the date of application (Sharma, 2007). This Act prohibited any kind of reverse engineering and process development by domestic companies. There were few domestic firms in the pharmaceutical sector and these were not capable of local production of bulk drugs due to lack of required technological capabilities. As a result of strong patent protection and absence of competition from domestic firms, foreign firms were charging higher prices for their products in India. The independent government in 1947 emphasized rapid industrialization and invested heavily in pharmaceuticals yet did not discourage foreign companies for competing in India. In the first decade of independent India i.e. in between 1947-1957, 99% of the 1704 drug and pharmaceutical patents in India were held by foreign national enterprises which controlled 80% of the market (Dubey, 1996). As a result, even after independence, foreign held patents ruled the Indian pharmaceutical industry and US Senate Committee headed by Kefauver in 1962 had observed that drug prices in India were the highest in the world (Hamid, 1993).During this time, government took a major step to make the pharmaceutical industry self-reliant with the establishment of two giant public sector enterprises, namely the Hindustan Antibiotics Limited in 1954 followed by Indian Drugs and Pharmaceuticals Limited (Pradhan and Alakshendra, 2006). These two companies played an important role in starting the domestic production of key bulk drugs.

2.1.1 Post Independence Technology Efforts (Early Years)

These initiatives in investing public sector by the government were not enough to start the local production of pharmaceuticals. A system which encouraged technology acquisition, transfer, diffusion, development and innovation was the need of that hour. Meanwhile, to provide suggestions on the type of patent system that India should implement, two expert committees were established in independent India which suggested that a patent system, which focused on the access to the resources at lesser
prices, to counteract monopoly abuses by multinationals and to promote the local industry, would be beneficial to India (Kiran and Mishra, 2011). Then, the Patent Act of 1970, which came into effect in 1972, was enacted on the recommendations of these committees and only process patents were allowed for pharma products under this Act. Various phases are represented in Figure 2.1 which depicts the slow and steady development of Indian pharmaceutical industry (Sreedhar et al., 2011).

![Figure 2.1: Phases of Indian pharmaceutical industry](Reproduced from Sreedhar et al., 2011)

### 2.1.2 Post-1970 Technological Progress

Indian Patent Act 1970 abolished the product patents for pharmaceuticals and reduced the patent term to 7 years from the filing date or 5 years from the sealing date, whichever was earlier. The Act also had a provision for invoking compulsory license (a license to use a product under reasonable and non-discriminating terms) after three years if a price was deemed unreasonable. It started the era of reverse engineering, where firms developed new products by simply changing a few steps in their production...
process, adaptation and process development. A large number of Indian domestic firms came into being by developing new cost-effective processes for drugs developed abroad and successfully competing with foreign firms operating in India as well as exporting to third countries (Dhar et al., 2002). The generic pharma industry in India thrived on process patent and it enabled the emergence of a competitive domestic industry (Chadha, 2009). Process patent regime was more suitable for countries like India with nascent pharma industry which lacked the technological capabilities and financial resources to compete with the big pharma MNCs at that point of time. During this period, firms did not seek foreign technical assistance. Indian manufacturers were able to imitate the patented drugs by using the information provided in the patent title owing to their well developed chemical infrastructure and process skills. Using this skill, the share of the domestic sector increased from 62 percent in 1974-75 to 82 percent in the case of technology intensive bulk drug production and from 49 percent to 60 percent in the case of formulations (Pradhan and Alakshendra, 2006). In the production of the bulk drugs and formulations, the share of foreign firms got reduced to 18 and 40%, respectively. This decline in the share of production was due to relatively phenomenal rise of production by domestic enterprises. Some firms like Ranbaxy, Dr Reddy’s Laboratories and Sun Pharma started focusing on novel drug delivery systems, thus adding their own inputs and values to the existing products. The products produced in this way were better tailored than MNC drugs for the Indian market (Smith, 2000). Pharmaceuticals like Cipla, Cadila, Lupin, Torrent, Wockhardt and Dabur also established large production facilities in India and started improving their manufacturing efficiency and technology (Chaturvedi and Chataway, 2006). Indian firms captured global headlines at the end of 1990s, when they announced their intention to manufacture and sell combination of anti-AIDS retroviral drugs for a fraction of costs being charged by the western firms that had originally developed these drugs. Even the U.S. Food and Drug Administration attested to the quality of Indian pharmaceutical manufacturing. By 1999, it has certified 193 Indian manufacturing plants as complying with its regulations and standards for production for export to the US market (Arora et al., 2008).

The negative impact of Indian Patent Act 1970 was that too many small and medium players entered the pharma industry, MNC’s reduced their launch in India and the basic
research and development and innovative activities were forgotten. There was no incentive for innovation in the absence of IPR protection.

2.2 The Indian Patent Law and TRIPs Regulations

The liberalization era that started in 1991 also affected the Indian pharmaceutical industry. In 1994, the Government of India introduced the “New Drug Policy” that reduced the drugs under price control from 347 to 73 in 1995 and 39 in 2002 (Chadha, 2005). Around the same time, India signed Trade Related Aspects of Intellectual Property Rights (TRIPs) in 1994 and World Trade Organization (WTO) came into being in 1995, creating awareness about the commercialization of intellectual property rights. Regarding the enforcement of WTO provisions, TRIPs provided a transition period till January 1, 2005 for developing countries like India that did not provide product patents in pharmaceuticals, food and chemicals as on January 1, 1995 (Lalitha, 2003).

However, Article 70.8 required these developing countries to provide a means for the acceptance of applications for product patents with effect from January 1, 1995 itself with the setting up of WTO. In addition, under the Article 70.9, Exclusive Marketing Rights (EMRs) were provided during the transition period for a period of five years from the date of obtaining marketing approvals in that country or until a product patent was granted or rejected, whichever was earlier, provided certain conditions were met. Thus, the combined effect of Article 70.8 and 70.9 through pipeline protection and EMRs was to provide the same protection for pharmaceuticals and agriculture chemical products as would have been available under product patent regime from the date of entry into force of TRIPs or January 1, 1995 (Chadha, 2005). In keeping its commitment under TRIPs, India introduced the Patent Amendment Act 1999, which granted inventors pipeline protection through a ‘Mailbox’ system i.e. while applications for product patents were to be accepted, grants were to be kept pending till the time product patents were introduced in 2005 (Chaudhuri, 2005). The amended Patent Act provides for limited compulsory licenses for EMRs.

The Patents (Second Amendment) Bill 1999, which was enacted in 2002, paved the way for stronger patent rights in India (Mukherjee, 2006). Under Section 53(1) of the amended Act, the patent term has been increased to 20 years from the date of filing of
the patent application, whether for product or process patents. Under Section 48, patent owners have the exclusive right to prevent others from making, using, selling or importing the invented product or process in India. Under the original 1970 Act, importing was not mentioned as an exclusive right. Section 10A has been added relating to the reversal of burden of proof in case of infringement suits. A new set of provisions under Section 107A have been added to permit pre-market testing of generics during the patent term to enable them to be marketed immediately upon expiration of the patent under Bolar provision (Mathur, 2001).

Finally, product patents were introduced for pharmaceuticals and agricultural chemicals with the enactment of the Patents (Third Amendment) Act, 2005 in March 2005 to meet India’s commitment to the WTO regarding the enforcement of product patents. The Act has provision for granting compulsory licenses to enable export of patented medicines to countries with inadequate or no manufacturing capacity to meet public health emergencies such as HIV-AIDS (in accordance with Doha Declaration on TRIPs and Public Health 2001). It provides for both pre and post-grant opposition to a patent grant by streamlining the procedures for opposition and does away with the provisions relating to EMRs (Chadha, 2005).

The TRIPs consistent patent law addressed three sets of issues from the perspective of Indian pharmaceutical industry. First, the adoption of new definition of “Pharmaceutical Substance” which should be new entity involving one or more inventive steps. The second is the “exclusion of mere discovery of a new form of a known substance” and “the new use for a known substance”, which could prevent grant of patents on formulations. Third issue was protecting the interests of the producers who were already producing the products and that may be granted patent protection in the new regime. All the patent applications were accepted as mail box applications and were examined after the product patent regime was introduced in 2005 (Dhar and Gopakumar, 2006). Thus, with the third amendment regarding product patents, India is obliged to provide strong patent protection rights and the pharmaceutical industry is again facing competition from MNCs necessitating greater R&D efforts since Indian firms can no longer survive on the basis of reverse engineering.
2.3 Status of Pharma Small and Medium Enterprises (SMEs) in India

While there is a growing appreciation about the role of strategic government policies on the competitiveness of Indian pharmaceutical enterprises, the issue is less analyzed in case of small and medium pharmaceutical producers. Most governments are placing an increased emphasis on creation and development of SME sector because SMEs contribute in the national economy in terms of their contribution to GDP, employment generation and export performance and in achieving economic development of the nation (Burrone and Jaya, 2003). The large Indian pharmaceutical industry has been experiencing rapid growth with significant advancement in domestic technological capabilities. However, SME sector is characterized by low technology levels and is facing tough competition from their global counterparts due to globalization and many obstacles to fast development. This acts a major handicap in the growth of SME sector in the emerging global market. It is a thus a challenge as to how the SMEs embrace the new technologies to leap frog and contribute significantly in the inclusive growth program.

Since 1966, the policy definition of small scale industries (SSI) in India is based on the critical value of gross investment in plant and machinery with continued revision in the critical limit. The upper cut-off value of plant and machinery for the pharmaceutical small scale industry had gone up from Rs 1 million in 1975-76 to Rs 2 million in 1980-81 and then to Rs 10 million in 1999-00. From June 2003 onwards, the critical limit for pharmaceutical SSI has been revised to Rs 50 million (Pradhan and Sahu, 2008).

The Micro, Small and Medium Enterprises Development Act (MSMED Act, 2006) was imposed by the ministry of Micro, Small and Medium Enterprises, Government of India, in October 2006 and it is geared towards the promotion and enhancing the competitiveness of small and medium enterprises. This Act established a national board for MSMEs and its main function is to oversee and regulate the development of MSMEs in India. The board’s duties include monitoring cluster development, training enterprises, development of infrastructure and promoting financial access to MSME section in the country (Raju, 2008). For the first time, the Indian industry policy regime provided a standardized definition for medium and small scale sector by the level of
investment in plant and machinery. The definition of SMEs provided in the manufacturing sector is different from that of service sector under this Act. Manufacturing sector includes the firms and businesses which involve the production, processing or preservation of the goods. When the investment in plant and machinery of a firm does not exceed Rs 25 lakh, then it is called micro enterprises. A small enterprise is that having an investment in plant and machinery ranging between Rs 25 lakh and Rs 5 crores. If the investment in plant and machinery is between Rs 5 crores and 10 crores, then it is said to be a medium enterprises (Jaswal, 2012; Ghatak, 2009).

The total strength of the Indian SME pharma sector is roughly around 9,456 units, comprising of both registered and unregistered bulk drugs, formulation units and units producing intermediates (Jinoy, 2012). 75% of these companies are purely manufacturing companies with their own facilities, 13% of the companies are engaged in manufacturing as well as trading, 10.5% of the companies are doing clinical testing and contract research along with manufacturing. About 1.5% of the companies are focused only on research and development. About 50% of the companies are engaged in export to various countries around the world including USA and Europe (Ray, 2010).

The technological activities of formulation units are manufacture of generics, fixed dose combinations and conventional dosage forms whereas bulk drugs units generally deals with process related activities related to generic drugs by small firms and new processes by some medium scale firms (Iyer, 2008). In the pharmaceutical sector, SMEs produce 40% of Rs 70000 crores worth medicines in India and they are also the largest employer of pharma sector (Nauriyal, 2006).

2.3.1 Challenges Faced by Pharma SMEs

Since the first Industrial Policy of 1948, the pharmaceutical SMEs have been facilitated by various favorable policies like exemption from the Drug Price Control Order (DPCO), preference in procurement of the drugs by government health programs, process patent regime permitting them to develop their own process of making a drug at a lower cost etc. (Pradhan, 2003). The Government of India has closely regulated the pharmaceutical sector and maintains a list of products reserved for manufactured by small scale enterprises. These include nicotinic acid, niacinamide, paracetamol,
parabens and their sodium salts starting from para- hydroxyl benzoic acid, calcium gluconate, benzyl benzoate, pyrazolone, aluminium hydroxide gels and para amino phenol industrial grade (Iyer, 2008). Pharmaceutical SMEs also benefited from other provisions like provisions of finance, training, technical, marketing, access to raw materials and other support measures. As a result of these interventions, small enterprises in spite of their resource disadvantages emerged as significant market players. The share of small Indian private sector in the production of bulk drugs went up to 26 % in 1985-86 from 17% in 1976-77 (Kumar and Pradhan, 2003) and they also played an important role in supplying essential life saving drugs at affordable prices.

But after 1991, the macro policy regime in India has undergone dramatic changes. For instance, permitting 100% FDI under automatic approval system and reduction in import duties on life saving drugs, bulk drugs and medical equipments have significantly globalized competition in Indian pharmaceutical market (Pradhan and Sahu, 2008). The adoption of product patent regime and emphasis on quality and good manufacturing practices are demanding higher technological efforts from small and medium firms (Das and Nair, 2004). With the strengthening of intellectual property rights protection system under TRIPs, pharma SMEs are unable to exploit the protected and exclusive products discovered and developed by large R&D based corporations and their licensees. The adoption of product patent regime gave a very tough time to survive in this competitive market for SMEs and generic companies, which were 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. Since small firms are often constrained by their size limitations in sales, investment or employment in R&D sector with limited financial resources, meeting these emerging challenges may not be resumed to be as smooth as in case of large enterprises (Pradhan, 2003).

A number of recent policy initiatives with respect to pharmaceutical sector reflect the shift from earlier protective regime to more of a facilitating regime. With the dilution of DPCO, the relaxation granted to pharma SMEs is no more relevant. Since 2005, firms participating in the tender for drug supplies to government hospitals are required quality certification e.g. GMP compliance certificate (Pradhan and Sahu, 2008). Thus, unless
SMEs upgrade their manufacturing facilities to GMP, they may lose their stable source of demand emanating from government procurement.

2.3.2 Importance of Intellectual Property Rights for Pharma SMEs

By issuing the patent ordinance, India met a WTO commitment to recognize foreign product patents from January 1, 2005, the culmination of a 10-year process. In this new scenario, the Indian pharmaceutical manufacturers will not be able to manufacture patented drugs (Mukherjee, 2006). The cumulative impact of these developments is a remarkable transformation of the environment in which SMEs operate, implying that sector has no option but to compete or perish. These industries can stabilize and survive if they are able to innovate with new products and processes to meet the market demand in time (Maheshwari and Bhatnagar, 2008).

To adapt to this new patent regime, the industry is exploring new business models and mechanisms, different from existing traditional ones. Intellectual property rights (IPRs) and technology transfer mechanisms are such mechanisms and two facets of knowledge, which are critical in making any industry globally competitive. These mechanisms play a critical role in knowledge diffusion, for strengthening industry and also leading to better products for the society (Bansal, 2006a). These mechanisms also play a crucial role in strengthening developing countries to be self-reliant and for their speedy economic development.

2.4 Intellectual Property Rights

Intellectual Property Rights are the exclusive rights granted by the state giving the owner the right to exclude all others from commercial exploitation of a given invention, new/ original design, trademark, literary and artistic work and/or new variety of plants (WIPO, 2003). By providing this exclusivity over the exploitation of innovations, the system of IPRs create an incentive to invest in scientific, technological and original R&D activity so as to reduce the risk of free riding by others while commercially exploiting products and process innovation.

Intellectual property rights may be used by the companies to meet a wide range of business objectives (Burrone and Jaya, 2003; Maheshwari and Bhatnagar, 2008). These can be used to obtain access to new market e.g. by licensing another company to manufacture a new or improved product based on a patented invention and/or protected
trade secret (Starein, 2002). IPRs enhance the reputation of a company as a technology leader through access to or ownership of key patented technologies and can create a corporate identity through a trademark and branding strategy. These rights help in avoiding wasteful investment in R&D by consulting patent data bases and learning about recent technological developments. Patent documents provide useful information on the state of the art, which would enable an enterprise to avoid unnecessary wastage of resources in terms of money and time during the R&D process. Patent information can provide useful information which can lead to product improvement or to design new inventions, which may help to shorten the lengthy time frame often required taking a new product to the market (Kalanje, 2006). IPRs can be used to establish joint ventures, strategic alliances or other types of partnership with other companies, setting up of a franchising system on the basis of the company’s trademarks and other IP rights. The market value of the company is increased in case of merger or acquisition (WIPO, 2003). Companies can obtain additional revenues through licensing or sale of IP rights and these provide access to new financial opportunities or support a request for funds from a financial institution, bank or venture capitalist.

The strategic use of IPRs by SMEs will depend on company’s overall strategy. Thus effective management of IPRs may provide new business opportunities for companies with the appropriate skills, innovative capacity and resources to benefit from the range of options offered by the IP system.

2.4.1 Strategic use of Intellectual Property in Pharma Small and Medium Enterprises

Literature reveals many small and medium enterprises which have benefited from intellectual property rights. FK Biotech, a Brazilian firm specializes in research, development, production and distribution of immunodiagnostic kits and its product line comprises of over 70 products. It is currently developing an expert vaccine composed of cancer cells that work as medical treatment as they are capable of stimulating the immunological system to fight against cancer. The company relied on patent information for identifying new technologies, niche markets and potential licensors from which to acquire leading technologies. FK Biotech also invested in registering its trademark which is crucial for the development of the company’s marketing strategy (Ferrer *et al.*, 2004). Similarly, Therabel Pharma, an Argentinean SME set up in 1990,
is devoted in the preparation of pharmaceutical and cosmetic products. Therabel recognized that it is by means of innovation that SMEs can compete with large firms and subsidiaries of foreign companies in the local market. The firm recognized that by means of intellectual property protection for new products and processes, it is possible to preserve local supply of drugs (Martinez, 2010). Another company that relies heavily on R&D and the protection of results through the intellectual property system is Laboratorios Sophia, a Mexican company that has high level of participation in the national market for innovative ophthalmological products (www.wipo.int/sme). The technological information search system is used constantly in different databases available.

In biotechnology, Shanta Biotech Group, an Indian small scale industry has indigenously developed low cost vaccine for Hepatitis B with limited resources. ‘Shanvac’ is India’s first recombinant DNA vaccine, a specialty in which global drug companies have a monopoly, thus indicating that those who have the latest technology do not finish the race first, the prize often goes to the entrepreneurs who can utilize technology to create sound businesses (Venkatesan, 2001). An Indian Scientist, Dr Pushpa Khanna has also invented a drug named Gourdin, which is a hypoglycemic polypeptide extracted from the seeds of bitter gourd. The product has been granted patent in India, US, Australia, EU, China, Malaysia, Korea and Japan. The product was commercialized in 2000 and is currently manufactured by M/S Pushpa Jyoti Herbal Enterprises, Gurgaon (Kumar, 2006). The technology for this product has also been transferred to China, Malaysia, Korea and Japan. Similarly, in 1998, a method for producing a novel fiber in powder form from the discarded leaves of plant Aloe ferox was patented by South Cape Aloe, a virtual start up company in South Africa with strong emphasis on technology and IP. The product was developed to treat Irritable bowel syndrome (IBS) and AIDS related diarrhea (ARD). SCA granted Baylabs, a manufacturing company, exclusive rights to make the powder and gained the share hold in Baylabs in exchange for exclusive, royalty free, world wide rights to export the powder (Martinez, 2010). The Baylabs example illustrates how the development of a patented technology can have positive commercial and moral outcomes. Through the creation of strategic alliances and patent licenses, opportunities can arise for securing and developing IP for the benefit of society in both developed and developing countries.
Since successful innovation includes taking a new product to market, other IP tools also become very relevant. Above all, trademarks and industrial designs play an important role in the marketing process. Trademark is a useful tool which can also be useful in extending commercial benefits beyond the life of patent as in the case of Aspirin®. Aspirin drug was patented in 1899 by the Bayer Company. Knowing that patents have a limited duration, Bayer Company embarked upon promoting a trademark for its new product. When the Aspirin® patent expired, the company continued to benefit from the sale of aspirin through its established trademark Aspirin® (Drucker, 2005). Thus, strategic use of a combination of IP tools in the innovation process can significantly contribute to higher profits and maintenance of market position which ultimately enables technology-based innovative SMEs to a high return of investment (Kalanje, 2006).

### 2.5 Transfer of Technology

As a result of globalization, changes in the competitive and market pressures, the demands upon both large and small businesses for new technology are increasing. Companies that have been able to survive for many years by offering mature products to market but investing minimally in product and process innovation, are finding it increasingly difficult to compete in today’s demanding and fast-paced world. In order to survive, compete and prosper, businesses must learn to monitor technological development, react quickly to changes and to renew and improve their products and processes regularly. Intellectual property is one of the methods by which the countries can progress but every country does not have the capability and capacity to create intellectual property that will help to achieve social, technological and economic development. Such countries can acquire and master the technology through acquisition, adaptation and utilization of technical and technological knowledge from another country in which the knowledge was originated (Murphy, 1985).

Transfer of technology (TOT) is defined as a process by which a developer of technology makes its technology available to a commercial partner that will exploit the technology (Mendes, 2006). Generally, technology transfer is the sharing of knowledge and facilities among federal laboratories, industry, universities, federal, state and local governments and third party intermediaries. The purpose of technology transfer program is to make federally generated scientific and technological developments
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accessible to private industry and state and local governments. These users are then encouraged to develop the technology further into new products, processes, materials or services that will enhance a nation’s industrial competitiveness or otherwise improve the quality of life (Technology Transfer Definitions, 2004). In its most basic form, technology transfer includes the transfer item itself, the developer of the technology, various channels to accomplish the transfer and the technology recipient (Rogers, 1993).

**2.5.1 Technology Transfer in Pharmaceutical Industry**

Pharmaceutical industry is resource and knowledge intensive, technology driven, high risk, high profit and long process industry (Janodia et al., 2008). The development of various drugs and therapies take several years, billions of dollars and different phases where regulatory approval is mandatory before marketing any product.

![Figure 2.2: Typical New drug development time scale](Reproduced from Domb and Mlodozeniec, 2004)

Fig. 2.2 shows the time scale and the financial investment in each of the four phases of the drug development (Domb and Mlodozeniec, 2004). It is estimated that approximately $800-900 million are required to find a new molecule and it requires 10-12 years of consistent efforts and synthesis of thousands of molecules to commercialize a drug successfully.

At the same time, there are a number of stages of drug development i.e. laboratory and animal studies (3-4 years), Phase I clinical studies (1 year), Phase II studies (2 years),
Phase III clinical studies (3 years), review by Drug Controlling Authority (2-3 years), where there is no return on investment and the chances of success are extremely low (Mulaje et al., 2013). It was estimated that only one in thirteen molecules reach market (2000-2002) when compared to one in every eight molecules previously (1995-2000) (Figure 2.3). Attrition has been particularly severe in Phase III clinical trials (Sreedhar et al., 2011). There is no other industry which can be compared with the drug industry for such a long chain of efforts and such a high risk from the stage of discovery of molecule in the laboratory to the stage of approval to reach the market place.

![Figure 2.3: Number of molecules through preclinical to launch](Reproduced from Sreedhar et al., 2011)

The drug research in today’s context is a multidisciplinary activity encompassing design and synthesis of compounds, bioactivity, screening, toxicity studies, pharmacokinetic studies, bioavailability etc. Thus it needs expertise in areas such as medicinal chemistry, molecular modeling, biochemistry, microbiology, toxicology and pharmacology etc.

Many pharmaceutical firms do not possess the capacity to develop and market the molecules till the end stage and are interested in transferring technology to big pharmaceutical firms that have financial and manpower capacities. Thus there are different reasons why a developer of technology might consider making the technology available to another person or firm to exploit instead of exploiting the technology itself (Mendes, 2006):

1. Forming alliances with partners that can progress the development of the technology to take it to the market: The developer of the technology generally have the resources to take the technology to a particular stage of development, such as up to animal studies and toxicological studies but does not have the resources to take the
technology through its clinical and regulatory phases. Thus, it partner with another organization to take it through these phases, and into the market.

2. Forming alliances with partners with manufacturing capabilities: The developer of the technology may have taken the technology to final state of development but the facilities, resources or capabilities to manufacture the product are lacking.

3. Forming alliances with partners with marketing and distribution capability: The developer of the technology generally have fully developed technology and even have regulatory approvals and product registrations for the product to be marketed, but it lacks the marketing and distribution channels to give it a marketing capability, and thus partner with another organization that has the capability.

4. Exploitation in different fields of application: The developer of the technology might be capable of exploiting the technology in one field, such as diagnostic applications but might not have the capability to exploit in another field, such as therapeutic applications. The developer of the technology may pursue exploiting the technology itself in diagnostic field, and may grant exploitation rights to a commercial partner for the exploitation of therapeutic applications.

5. No commercial capability: The developer of the technology may be a university or a research institute which does not have the capability to exploit commercially, and needs to collaborate with another organization that does have the capability.

In each of these cases, the developer of the technology or owner has decided that it may not have the capability or resources to take its technology further, and has decided to partner with another person that can do so.

In the exploitation of pharmaceutical products, technology transfer by partnering in this way to bring a pharmaceutical product to market is a common feature of the industry.

2.5.2 Strategic use of Technology Transfer in Pharma Small and Medium Enterprises

Tianzu and Gang (2001) have studied various modes of technology transfer by small enterprises of China and emphasized that the key to development of small enterprises is not technologies itself but the technical capability of small enterprises. In a successful case study of technology transfer by assigning R&D to Shanghai Institute of
Pharmaceutical Industry (SIPI), a small firm, Huahai Medicine Co. Ltd. grew at a rate of 60% per year and ultimately became a large enterprise. In the similar way, the Industrial and Technical Consultancy Department has transferred Thai Institute of Science and Technological Research (TISTAR)’s innovative technologies and R&D to Thai SMEs to help them optimize commercial production. Production of an antifungal cream from lemon grass, steroids from sisal agro-industrial waste and fish oil containing omega-3 PUFA from boiling water out of tuna canning industry are being carried out successfully (Antarikanonda and Lerdthusnee, 2003). Mishra (1996) discussed the technological upgradation and technology transfer activities in Nepal and suggested that the investment for R&D can only be meaningful if the achievements in the field of new technology are adopted and utilized by SMEs concerned. This necessitates the establishment of a national agency which will promote the technology transfer and commercialization of new technology that are generated in the universities, industries and government research laboratories.

This is especially relevant for developing country like India. To become economically self-reliant, the role of a catalytic agent, which acts as a via-media of technology transfer operations, is very important. The National Research Development Corporation (NRDC), New Delhi is such an institute, which act on behalf of innovator, be it a laboratory, a university or an individual, to exploit research ideas for commercial purposes. NRDC has different methods of funding its technology development, transfer and promotional activities in the form of technology development loan, equity participation and by providing techno commercial financial support. The corporation has funded a development project for the setting up of a disposable blood bag plant at Thiruvanthapuram, Kerala, India. After successful commissioning of the plant and marketing of the product, NRDC has further licensed the technology to three more parties in the country (Bhuvaneswar and Ranjit, 2005). It has also funded a development project for the pilot production of heart valves for clinical trials at Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvanthapurum, Kerala, India. After successful clinical trials, the technology has been licensed to M/S TTK Pharma Ltd, Chennai, India. Similarly, the process know-how for Spirulina, a high quality food supplement, was developed at SMC research centre, Chennai and NRDC
has licensed know-how and provided technology development loan for setting up of commercial plant (Narayanswamy, 1997; Ganguli, 2003).

2.5.3 Mechanisms of Transfer of Technology

The transfer of technology from one organization to another can occur in a number of ways with each mechanism having its own advantages and disadvantages. Following are some of the important mechanism by which transfer of technology occurs (Cohen, 2004).

a) Patent licensing agreements (PLA): These licenses allow the other party (only private sector) to use the invention for its own purposes for a specified time and in exchange for a fee (royalty) to be paid to patent holder. The patent holder may license partial interests (one half, one quarter) of a patent. Licensing agreements can exist with several different users or one user (Swaminathan, 1994). Ground rules are set in PLA that if broken, can cause termination of the agreement. Termination of the agreement can be the result of an improper execution of the original plan, a willful false statement or omission made in the license application, a breach of the license, or passing of the government regulation stating that this patent is subject to public use. Termination may also occur by mutual consent of both parties.

There are four main types of patent licensing agreements:

Non-Exclusive: A non-exclusive agreement allows more than one company to utilize the licensed technology. Lower licensing fees and reduced royalty fees reduce the cost of product, which in turn can increase the market opportunity (Bastani et al., 2004).

Partially Exclusive: The same technology may be licensed again for a different geographical area or for a different application.

Exclusive: The organization granting the license may not license the same technology again to another party.

Co-Exclusive: Exclusive rights to commercialize a technology may be shared by several organizations.

b) Conferences, symposia, tradeshows and workshops: Membership in industry groups and professional associations is a very important tool in assisting transfer of technology. It is through these organizations that commercial contacts are made, new
ideas germinate, current ideas are built upon, information flows, training can take place and the preliminary steps of transfer of technology naturally occur. Expositions and trade shows provide opportunities for institutes to other laboratories to showcase technologies to potential partners and to take the all important step of obtaining exposure for its capabilities and achievements.

c) Technical assistance: Frequently, technical assistance is used for transfer of technology via telephone enquiries or other contacts. It is important that the laboratory person does not cross the role of consultant. Answering direct technical questions is appropriate, but giving subjective guidance and acting as an advisor/consultant should be avoided.

d) Personnel exchange: The exchange of personnel between the two parties is an important means of transfer of technology. Through this, each party gains insight into the problems of the other partner. This helps to facilitate the transfer of technology between research institute and industries. The benefits of personal exchange are extensive.

e) Use of laboratory facilities universities, industry, technical community and other government facilities may utilize equipment and expertise as research institutes.

2.5.4 Importance of Technology Transfer and Commercialization

The transfer and commercialization of the findings of life sciences research has demonstrated benefits for health care, the productivity of the university researchers and their institution and local economic development.

i. Improvement in health care: Developed countries have benefitted greatly from research in life and health sciences. The evidence is especially strong in the area of cardiovascular diseases but persuasive cases have been made for the treatment of diabetes, specific cancers, degenerative joint diseases and mental illnesses (Cutler and McClellan, 2001). An analysis of the US industry patent citations found that the researchers in academic institutions authored half of all the papers referenced on drug patents between on drug patents between 1993 and 1994 (Narin et al., 1997). Another study estimated that 27% of the new products and 29% of the new processes
commercialized by drug companies in 1980s would have encountered long delays in development were it not for academic research (Mansfield, 1991).

**ii. Increased research productivity:** Findings from a 1994-95 survey of more than 2000 life sciences faculty in US found that those with industry funding published many more articles in peer-reviewed journals than the faculty without industrial funding (Campbell et al., 2004). The potential explanation for this relationship may be that industry funds scientists who are already more productive or that industry funding provides additional resources to faculty which in turn increases their productivity. Industry associated research is also associated with an increased likelihood of commercialization activities among faculty and institution. A 1996 survey found that faculty with industry support were likely to have applied for a patent, had a patent granted or licensed, had a product under review or started a company (Blumenthal et al., 1996). Faculty can also benefit from commercial activities in the form of additional income from licenses, royalties and sale of equity, as well as increased intellectual stimulation by seeing the practical applications of their research. At an institutional level, increased commercialization by faculty can translate into increased revenues and additional research funding.

**iii. Local economic development:** Technology transfer can have a substantive impact on regional economies. University researchers and their institutions played an important role in the establishment of local high tech industries in a number of scientific fields including biotechnology. Scientists at Massachusetts Institute of Technology (MIT), Harvard University, Stanford University and University of California have played pivotal roles in founding local electronics and biotechnology companies e.g. Genetics Institute, Biogen and Genentech (Dorfman, 1983). In turn the development of these industries has created high paying technical and professional jobs e.g. it has been estimated that MIT graduates have founded 4000 firms which in 1994 alone employed at least 1.1 million people and generated $232 billion in sales (Massachusetts Institute of Technology, 2003).

**iv. Enhancing technology transfer from developed countries to developing countries:** The Office of Technology Transfer (OTT) of US National Institute of Health (NIH) has increased its technology licensing pertaining to neglected diseases to partners
in developing countries. Establishing the partnership through the transfer of technologies and assisting the indigenous institutions in building their R&D capacity impacts the policies on protection of IPRs and increase MNCs investment in lesser developed countries. By enabling indigenous institutes to develop NIH technologies in these regions, local capacity in R&D, market competitiveness, experienced work force and scientific excellence has immensely improved. The biotech infrastructure has grown and it has ultimately helped in strengthening and stabilizing the developing countries’ economies (Salicrup and Fedorkova, 2006). Many successes of these partnerships already exists e.g. the production of Hepatitis B vaccine by multiple Indian companies, the recombinant human insulin vaccine developed and produced in Brazil in 1990s to meet its population needs. Such type of transfer can provide solutions to the most socio-economically harmful diseases. The OTT has already transferred early stage technologies to public and private institutes in India, Brazil, China, Korea and Mexico. Out of these transferred technologies, the Serum Institute of India has undertaken the manufacturing of the conjugated meningococcal vaccine for eventual distribution in Sub-Saharan Africa, Middle East, Latin America and Eastern Europe (Salicrup et al., 2005).

v. **To induce investment in academic institutes:** Universities believe that the primary purpose of their technology transfer is to induce investment in university technology by private firms to bring the products based on technology to the public.

vi. **To assure access to the medicines and vaccines in the developing countries:** Universities should use patents in a way that it does not inhibit the distribution of medicines to the developing countries at accessible cost. University technology transfer offices are to make changes in their licensing practices for patents relevant to health care in developing countries. Nelsen (2003) has mentioned few strategies that universities and other research institutes may try their quest to provide access to new medicines in developing countries. At the time of licensing, universities can ensure that the license will be used to advance the efforts to meet the health care needs of developing countries.

vii. **Strengthening small and medium pharma enterprises:** Small firms often face many obstacles to fast development. First, there is the perennial problem of insufficient
funds for acquiring advanced technologies to enhance production quality and lower the costs. Second, small firms can’t compete with large ones in attracting sufficient qualified workers and experts.

2.6 Barriers Faced by SMEs in Using the IPRs and TOT Mechanisms

SMEs face a number of difficulties in using these mechanisms. This is often the result of their limited knowledge of the ins and outs of the IP system, lack of clarity about its relevance to their business strategy and competitiveness, finding the system too complex and expensive to use (Maheshwari and Bhatnagar, 2008). The propensity in the use of information contained in patent data bases is quite low among SMEs. For most enterprises, trade fairs and information from suppliers remain the preferred source of information. This is because of their lack of awareness of the wealth of information available in patent documents (Starein, 2002) limited skills to conduct patent searches and inability to interpret the claims in patent documents. As compared to large enterprises, SMEs are also less likely to engage in technology transfer and innovation activities. The primary obstacle SMEs perceive with regard to new technology development is learning about and gaining access to external technology development and support options (Jones and Jain, 2002). Indian government has adopted various policies in terms of possible solutions to the problems faced by SMEs and promoting interaction between universities, public R&D centers and SMEs in the field of innovation and technology transfer has been the main target. It is generally felt that a closer interaction between universities and industry would enable enterprises (and society as a whole) to benefit from the innovative capacity of the universities. Industry-institute partnership thus holds the key to innovation and technology development.

2.7 Industry-Institute Linkages

The beginning of 21st century is witnessing the advent of a knowledge driven society and the demand of higher education in today’s world is rapidly growing as it helps in creation of knowledgeable individuals who will ultimately serve the society. But many of the Indian higher education institutes have failed to fulfill the demand of skilled and specialized manpower which possess the creative thinking and specialized skills required by the industry. Institutes can boost the value of products in the form of knowledge and industry can supplement the value of institutes in the forms of funds
(Nangia and Pramanik, 2011). The National Policy of Education (National Policy on Education, 1986) in India has put great emphasis on the need for industry-institute linkages and the dynamic role of this collaboration in strengthening national technology building and international competitiveness is increasingly being recognized. However, in spite of many efforts undertaken by central and state governments, industry-institute interaction in India is an unexplored area with the possible exception of few studies.

Literature has provided some technological as well as competitive reasons for linkages between research institutes and industry (Cohen, 2004). Developing new technology based products is expensive; linkages may reduce the perception of risk. As technologies are being developed there is great deal of uncertainty as to outcome. Linkages provide some assistance in overcoming this uncertainty by increasing the options available. Linkages may reduce the element of risk embedded in innovations. When new technologies emerge, but their potential has yet to be proven, companies may choose not to invest in them to any extent but to keep a “watching brief” on their development in research institutes. Linkages may be the way that firm chooses to see how new technologies are shaping up.

The linkages may be created in order to set up a major front against competitors by keeping in touch with latest developments. These may also assist the establishment of standards. Firms may feel themselves to be in a better position, when approaching regulatory authorities, with a proposed standard which has been jointly developed.

2.7.1 Factors Affecting Industry-Institute Linkages

Santoro and Gopalakrishnan have studied the relationship oriented factors between industry and institute and found that trust between the partners and their geographic proximity is more significant than the communication effectiveness (Santoro and Gopalakrishnan, 2001). Large sized firms have greater technology transfer activities with academia due to their slack resources but it was shown that even smaller firms can be effective in the technology transfer process when it is in the geographic proximity of the academia. Santoro and Chakrabarti have shown in their study that since large firms are usually endowed with more resources, they have the ability to diversify into non-core areas i.e. which are not central to the firm’s core business (Santoro and Chakrabarti, 2002). Unlike their larger counterparts, small firms are usually most
concerned with survival and therefore, participate more in industry-institute relationship that provides immediate solutions to the critical issues affecting central business areas and core technologies. In a similar study by Mansfield and Lee, it was indicated that the contribution of major research universities in the industrial innovation is highly significant but at the same time “second-tier” departments with adequate to good facilities also play an important but underappreciated role in this regard (Mansfield and Lee, 1996).

2.7.2 Types of Relationship between Industry and Institutes

A number of studies attempted at analyzing the channels through which knowledge flow from universities to industries (Kneller, 2001). These channels could take various forms depending upon the type of cooperation and the type of industry and research institute involved. These channels include:

a) Consultation and fee for service: Under this model, academia works with any industry for a stated period on a targeted research project. The benefit to the industry is the accrual of the data and for academics it is the funding. Publications may or may not be generated. The chances of leakage of institutional intellectual properties are quite high in this case; therefore, transparency, formal documentation and clarity are quite crucial. (Chin-Dusting et al., 2005)

b) Competitive grants sponsored by industry: Grants sponsored by industry are similar to the grants from other funding bodies. Industries used to support the research by contribution of unrestricted funds and equipments but in the present days the scope of research to be funded is targeted and clearly indicated as the research project is generally of industrial interest. These specific projects provide industry with knowledge and new technologies in the long run.

c) Industrial sponsorship of training and educational program: These relationships range from sponsorship of post-graduate students to post-doctoral fellowships. These are generally of two types, those in which students work in an industry and those in which students work in an academic environment but whose stipend comes from industry. In the former case, the student understands the reality of different types of works and it sensitize them to real world situations and in doing so it make them better
prepared for their own entry into the world of employment. The understanding of underlying concepts is also strengthened which they are supposed to have learnt (Yashpal Committee Report, 2009).

d) Industrial sponsorship of investigation-led research: The academic’s research project or a program is sponsored either partially or completely by the industry. The negotiations are done by academic institute and it also administers the partnership. Some institutes have set up very innovative processes of match making academics with the appropriate companies. An example includes development of low cost DNA rabies vaccine by Department of Biochemistry, IISc, Bangalore, in collaboration with Indian Immunobiologicals Ltd., Hyderabad. PCT application for this unique combination rabies vaccine (CRV), which is stable at room temperature, has been filed and pre clinical animal toxicity studies have been successfully completed and field trials in dogs have begun. Thus with a well defined benefit sharing arrangement between collaborating partners, a realistic market problem can be solved (Ganguli, 2003).

e) Academia, industry and government: Innovation is based upon ‘Triple-Helix’ of university-industry-government interactions. In this relationship, the entrepreneur university takes a proactive stance in putting knowledge to use and in broadening the input into the creation of academic knowledge. As firms raise their technological level, they move closer to academic model, engaging in higher levels of training and in sharing of knowledge. Government acts as public entrepreneur and venture capitalist in addition to its regulatory role in in setting the rules of the game (Etzkowitz, 2003).

2.7.3 Academic Spin-off Companies

Companies spinning out from academia, known as spin-out companies, are a phenomenon growing with time. The success of this concept is best exemplified with the formation of 344 new spin-off companies in 1999 only in US. The foundation of this concept was laid down by the origin of Genentech founded in 1976 by University of California biochemist Herbert Boyer and geneticist, Stanley Cohen from Stanford University with the help of venture capitalist Robert Swanson (Genentech, 2005). Genentech went public in 1980 and the first recombinant drug they marketed i.e. human insulin was licensed to Eli Lilly in 1982. Another landmark case is of Borean Pharma (www.wipo.int/sme), the technology platform of which was developed in the laboratory
of gene expression, University of Aarhus, Denmark. The patents were filed with the help of Danish Invention Center which supported the scientists after spin-off and provided financial support, coaching on setting the business plan, achieving marketing information and identifying the investors. Companies spinning-out from academia allow the academic scientist to maintain some ownership and management over their intellectual property. Spin-out company helps in bridging the gap between academia and industry.

2.7.4 Benefits for Industry-Institute Linkages

Since there is a rapid pace of technological change in many fields, the organizations are becoming obsolete in their skills and knowledge. The need to develop such linkages is to build a strong innovative environment in the country which will result in win-win situation for both industry and university. Thus collaboration between firms and universities can be beneficial to each others in many ways. Today there are various reasons for industrial firms and universities to work together.

Meyer-Krahmer and Schmoch have shown that acquisition of additional research funds is a major motive for university centers to co-operate with industrial firms (Meyer-Krahmer and Schmoch, 1998). The funding generated from the research helps in building infrastructure for future development. The benefit of knowledge exchange was also given the equal relevance. This supports the view that industrial firms also conduct significance research and are important producers of new knowledge (Santoro and Gopalakrishnan, 2001). Universities also want to expose students and faculty to the practical problems, create employment opportunities for their graduates, obtain internships for the students and gain access to applied technological areas (Santoro and Chakrabarti, 2002).

On the other hand, university researchers assume that the main interest of industry is the observation of recent scientific development i.e. the exchange of scientific knowledge with universities. The industrial researchers also need new knowledge to improve their running processes and products or to developing new one. Benefits to a firm include access to highly trained students, facilities (laboratories, expensive instruments and equipments) and faculty (scientists and technologists doing state of the art research in a
specific area) as well as enhanced image and reputation when collaborating with a prominent academic institute (Philips, 1991). Thus industry and institute should be seen as complementary and not competitors.

2.7.5 Benefits of Industry-Institute Research Collaboration in Pharmaceuticals

This interaction is characterized by interactive and collaborative program between academic institutions and industrial sectors for the attainment of certain reciprocally beneficial purposes and missions. With the opening up of economy, firms are realizing that it is impossible to compete in even in home front let alone globally, with the technologies purchased from foreign nations (Joseph and Abraham, 2009). This in turn is forcing the industrial sector to look to academia for new source of knowledge. So in order to survive and ensure growth, the pressure on industries is growing to advance their knowledge as well as technologies.

In the older patent regime, there was not much requirement for research in most pharmaceutical companies because the generics medicines manufactured with the help of knowledge available in public domain were enough for the company to carry on the business. But in the present scenario, with the implementation of TRIPs, pharmaceutical companies are becoming technology driven for which research is required to develop new technologies that can improve its products, lower the cost and bring more profits (Nangia and Pramanik, 2011). In the pharmaceutical industry, the necessity of shorter cycles for drug development encourages the pharmaceutical industry to collaborate more extensively with academia. In order to shorten the costly research program and speed up the process of drug design and development, the academia and industry are being brought on one platform. Thus while working on their core technologies, pharmaceutical industry can keep itself updated with potential leading molecules and therapeutics (Meijer and Wilting, 1997). Academia is generally recognized as the sole source of translational research and an important academic output is the development of research tools e.g. transgenic mice. But industrial scientists are also getting involved in raising some questions pertaining to basic research as exemplified by industrial scientists at SK French, who discovered an additional histamine receptor and a substance capable of blocking it (Black et al., 1972). This research and the availability
of histamine-2 antagonist enhanced academic research in the physiology of peptic ulcer diseases. Thus such involvement in research can make academia-industry collaborations very fruitful.

The cost of research and development in pharmaceutical sector has also been markedly increased because of the use of high-tech instrumentation and heavy investment requirement in advanced technologies. In principle, the opportunities to discover new therapeutic agents seems to be better in the present time but in the recent years, the number of new chemical entities (NCE) that reach the market are declining because tedious research activities and efforts at higher cost are required for these. A set of molecules entitled by USFDA are the priority new molecular entities (PNMEs), which are a type of drugs most likely to originate from academic research. Since 1990, the number of PNMEs approval has remained essentially constant at 12 per year on an average. At the same time, PNMEs were shown to decline from 19% to 9% of all drug approvals while NIH budget increased by 200% (Campbell et al., 2004). This trend has been attributable to the pharmaceutical industry’s increased focus on the reformulation of existing drugs and sale of generics. By bridging the university-industry gap, the industry can pick the potential leading molecules from the academia and new products can be developed and commercialized. An attempt to determine the origin of all new molecules and biological entities approved by FDA from 1998-2003 was done by Kneller and it was concluded that linkages between universities, biotech companies and pharmaceutical industries are important for the discovery and development of new drugs (Kneller, 2005). A similar analysis of 32 drugs indicated equal contribution of industry (53%) and non-industry (47%); from the latter universities alone made a major contribution. Thus it was suggested that majority of high impact, innovative drugs came about because of significant and synergistic efforts from both sectors (Maxwell and Eckhardt, 1990). The successful development of Paclitaxel as an antineoplastic agent with the potential to have an impact on a number of human cancers was possible as a result of significant contribution from individuals and groups with diverse areas of interests and expertise (Donehower, 1996). The advancement of paclitaxel from preclinical to approval stage required the close collaboration of individual investigators at academic institutions, the pharmaceutical industry (Bristol-Mayers Squibb) and the
National Cancer Institute. This is the prime example of the potential of this mechanism to bring novel therapies to patients with serious illnesses in a timely manner.

Another classic example of how public basic research can contribute to pharmaceutical innovation is of captopril, which prevents high blood pressure by inhibiting the conversion of angiotensin I to angiotensin II and it was the first compound in a new class of drugs called angiotensin-converting-enzyme-inhibitor or ACE inhibitors (Cockburn and Henderson, 1998). Its discovery built on two lines of publicly funded research performed in academic settings. The first line involved the identification and description of the renin-angiotensin system which was published in 1950s. The second line of public research originated in Brazil. Here, research into the cause of death from snake venom identified a natural substance that acts on its victim by fatally lowering blood pressure. In 1965, it was shown that this natural substance blocks the conversion of angiotensin I to angiotensin II. Armed with this public knowledge, the scientists at Squibb were able to synthesize the first ACE inhibitor in the early 1970s. Captopril was subsequently approved for marketing by the FDA in 1981.

2.7.6 Role of Research Institutes in the Innovation Process

The role of research institutes in the innovation process is natural because of their multidisciplinary nature, their competence in undertaking basic research, their reservoirs of knowledge and information and their ability to recruit young talent. Therefore these institutes must be incorporated in the national- development planning process.

Meyer has indicated that institutes are increasingly viewed as pro active contributors to the technological development and economic growth (Meyer, 2004). The institute’s mission of teaching and research of creating and disseminating knowledge is its primary contribution to society as a whole to the knowledge-based economy. But with this broad mission, the university has recognized that it can contribute more directly by playing an active role in working with the for-profit sector. It does so in a variety of ways such as traditional teaching and publishing and traditionally, perhaps, by engaging in collaborative research with industrial companies, by exchanging personnel, materials and equipment with profit sector companies, and also by licensing patenting university inventions and other form of new technology to industry for commercialization. This
dynamic involvement with industry creates new demands on the university to manage these activities so that the institution’s primary goals of education, research and dissemination of knowledge are not compromised, but rather are augmented, with conflicts minimized and managed. Generally this is accomplished through the development and implementation of university policies governing such areas as scientific integrity, conflict of interests and intellectual property (COGR, 2000).

For the universities and research institutes to be effective in stimulating innovation and industrial growth, they must cooperate with the industry but unfortunately this is not always the case in developing industries. The research institutes are concerned more with their own internal problems and expansion. On the other hand, industry is preoccupied with its own problems such as lack of adequate markets, institutional rigidities and insufficient infrastructure and is usually unaware that these institutes might have plausible solution to its problems. To bridge this gap in communication, effective linkage between industry and university should be established.

2.7.7 Barriers in Industry-Institute Linkage

In spite of various studies and concerns, a huge gap seems to exist between academia and industry. The poor or almost missing academia-industry linkage was observed in pharmaceutical sector (Gupta et al., 2009). Both the elements were observed to be working bipolar without knowing the specific needs and resources of each other. When ever research linkage was found to exist, it originated from personal contacts of investigators without the role of department or organization as a whole.

Many barriers have been observed to exist but the major barrier in academia- industry linkage from academician’s perspective is differences in research objectives between industry and academia. Jalote has emphasized that academics are involved with pure or basic research which generally does not has applied part to it (Jalote, 2006). Academia lacks the information about getting in touch with relevant industrial partner for research and they also have insufficient equipment and facilities in academic institution to support collaboration. There is lack of influence of these collaborations on academic promotions. Linkages between academia and industry depend upon the motivation of researchers and personals with-in the institutes. The absence of well-defined guidelines and preponderance of promotional policies that assess the work out-put in terms of
publications and not any technologies transferred, damage any enthusiasm for such linkages (Bansal, 2006b). An identifiable barrier that inhibit the firms from partnering in research with a university was investigated by Hall et al. (2001) and observed that intellectual property related issues are stumbling blocks for collaboration. The goal of both the parties in producing and protecting IP is innovation for the production of revenues but universities view IP not only as a revenue producing source but also as a tool in the advancement and dissemination of knowledge. Another serious concern is that such alliances limits the ability of academicians to publish the research findings in a timely manner as dissemination of knowledge is of paramount importance to scientific community. This concern has been taken care of by the passing of Bayh-Dole Act in the US which allows the patent and ownership rights to the universities on the inventions discovered on government funded schemes (Henderson and Smith, 2002). A significant barrier voiced by academicians in its alliance with industry is its secretive ways of working which severely limits the academic freedom. An example of harmful effect of academia-industry collaboration was the disclosure dispute in Olivieri/Apotex case (Nathan and Weatherall, 2002). In this case, the clinical investigator (Olivieri) was sued by the company (Apotex) for premature disclosure of the adverse effects which raise serious concerns about public-private partnership. For an effective linkage, the geographic proximity of both partners has also been found to be an important factor (Santoro and Gopalakrishnan, 2001).

From industry’s perspective, poor equipment, facilities and infrastructure for research in institutions and lack of information on research being done in institution are observed to be the major barriers in academia-industry linkage. Industry believes that there is lack of initiative taking people in academics. The academicians are generally locked into the world of publishing or patenting, and often do not go out of their way to think about commercialization (FICCI, 2011). Academic research is not found to be application oriented. Chakrobarti and Santoro have differentiated knowledge as tacit or explicit. Explicit knowledge is easily expressible and universities are generally engaged in delivering such type of generic theoretical knowledge which is codified and transmitted through papers, patents and presentations. On the other hand, tacit knowledge is not easily expressible and this type of knowledge is required by industry in order to implement new products or processes (Chakrobarti and Santoro, 2004). Thus, there
remains a gap between what industry needs and what universities are geared to offer. Gupta et al. (2003) have mentioned that industry clearly perceives interaction with lab to be important but the actual frequency of interaction is significantly lower. The biggest perceived barriers in the minds of industrial clients are the work style of these labs and the quality of technology developed in them. Lack of administrative support from the university is also observed by some industries (Kleyn et al., 2006). Because of the embryonic and sometimes arcane nature of university research, only a small portion of the results have the potential to be commercialized or to solve current practical problems.

Traditionally a structural mechanism for the industry to interact with the academia in universities is often lacking. The difference in two worlds is also in terms of their philosophies, cultural orientation and priorities. Different mechanisms can be opted in order to overcome these gaps and to make the boundaries more fluid e.g. by not engaging in theoretical and general type of research but also in problem type of research. The ability of academicians to abstract from the problem and solve it by conceptualization is not developed in industry as they are mostly busy in their day-in and day-out problems. This gap can be overcome if academicians can lend their conceptualization and general skills and industry can provide practical reality. An examination of various issues associated with academic institutes and industry collaboration was carried out by Nangia and Pramanik (Nangia and Pramanik, 2011) and a convergence of interests of researchers from both the sides was indicated. The academicians are also doing some applied research besides the basic one owing to the survival in this competitive world and there are some companies which go for publications after hiding the key factors in order to get their work assessed. With such similarity of research, a possibility of strong collaboration can not be denied.

Collaboration between two institutes is said to be working when individuals work together for a common goal. In the achievement of goals, it is not sufficient for all collaborators to be equal and it indicates that a distinction should be drawn between primary collaborator i.e. those who define the goal and secondary collaborators who contribute to practical work. It was suggested by Mainschien that failure to articulate this distinction in the roles leads to failure in the collaborations (Mainschein, 1993). In addition, there are other issues which pertain to academia-industry linkage i.e.
misalignment in time lines, poor communication between two sectors, withholding of information resulting in duplication of work and uncertainties over the coverage of intellectual property. Short term orientation of the industrial partnership, administration problems and less interesting topics has also been observed to be the obstacles in the successful collaborations.

While the available evidence, mostly from the developed world, indicates that interaction with universities and public research institutions (PRIs) is an important source of means of innovation in the manufacturing enterprises, in India, however, industry-university interaction is still in its infancy. A survey of 462 large industrial units spread across different industries indicated that even the large Indian firms are largely inward looking and depended mainly on their own manufacturing process, and customers as the major sources of knowledge for innovation. Neither universities nor PRIs have any important role as sources of information either in terms of suggesting new projects or help completing the existing ones. Only 11.3% of the firms claimed that they had any form of collaboration with a university or a PRI. While the overall level of interaction is found low, for those who have interacted, the collaboration has been a success in terms of achieving the objective (Joseph and Abraham, 2009). However, the firms in the SME sector are increasingly making use of the testing tool room and other facilities in the PRIs and universities. Though the relevance of interactive learning as articulated in the systems of innovation framework is yet to be adequately appreciated explicitly in the policy circles, some of the recent committees appointed by the government have underlined the need for greater interaction with the PRIs and universities.

With an objective to synergize the strength of publically funded R&D institutes and Indian Pharmaceutical Industry, the Government of India has launched several schemes for promoting this network. This includes The Drug and Pharmaceutical Research Programme (DPRP, www.dst.org.in), Technology Development Board (TDB, Annual Report 2008-09)), The New millennium Indian Technology Leadership Initiative (NMITLI, www.csir.in) etc. These programmes promote the establishment of new mechanisms and linkages to facilitate the development of new drugs by Indian industry and research institutes. These schemes intend to enhance the capabilities of pharmaceutical industry by bringing together the scientific expertise existing in the
country’s research institutions and industry on a joint platform through projects and are jointly funded by the government and the industry. TDB has recently taken new initiatives by investing in SME technology venture fund targeted at investing in start-up and early stage technology based companies. TDB has also signed MOU with several foreign institutes to promote, assist and fund the development of joint technology cooperation/transfer projects and for supporting SME growth via technology transfer, industrial research, technology development and innovation for the purpose of generating economic benefit. (TDB, Annual Report 2008-09). The CSIR led NMITLI involves about 287 public R&D institutes and 80 private industries; in six years of existence it was able to catalyze 57 R&D projects (NMITLI, www.csir.in). The major success stories of NMITLI are new molecules for tuberculosis treatment, oral herbal formulation for the treatment of psoriasis, the development of pure recombinant lysostaphin, a novel biotherapeutic molecule for Staphylococcus infections and scientifically validated herbal formulations.

2.8 Steps taken or Proposed to be taken by Government

The Ministry of MSME has recently instituted a significant step to enable small and medium enterprises to meet new technological and regulatory challenges by formulating a National Manufacturing Competitiveness Programme (NMCP) worked out by the National Manufacturing Competitiveness Council (NMCC) in consultation with industry (NMCP, www.dcmsme.gov.in). Under the aegis of this programme, a “major promotional package” has been announced to provide support to the SMEs in the areas of credit, technological upgradation, building awareness on intellectual property rights and marketing. Other steps proposed by the Central Government to enable the small and medium pharmaceutical companies to counter the competition from big pharmaceutical companies include:

1. Availability of financial assistance up to Rs 1 crore with 15% capital subsidy to small scale drug and pharmaceutical units for technology up-gradation under the credit linked capital subsidy scheme of Ministry of Micro, Small and Medium Enterprises (MSME).

2. Proposal of Department of Chemicals and Petrochemicals to extend 5% interest subsidy to pharmaceutical small scale units for technology up-gradation on the basis of Schedule ‘M’ of Drugs and Cosmetic Rules, 1945.
3. Support to high-risk pre-proof-of-concept research and late stage development in small and medium companies in the areas of diagnostics, immuno-biologicals and various industrial products like antibiotics, industrial enzymes, vitamins etc. under the Small Business Innovation Research Initiative (SBIRI) scheme launched by the Department of Bio-technology.

4. Subsidy on borrowings to SMEs to building necessary infrastructure for standardization of their products and development of Pharmaceutical SEZs which facilitates the availability of infrastructure, market access, boosts capacity utilization, encourages exports and facilitates excise relief.

The National Pharmaceutical Policy 2006 has also included some initiatives like reduction in excise duty from 16% to 8% and enhancement of the exemption limit for excise duty from Rs 10 million to 50 million for SMEs.