FOREIGN DIRECT INVESTMENT IN INDIAN PHARMACEUTICAL INDUSTRY

RESEARCH PAPER

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INTRODUCTION

Thirty years ago, Ray Vernon wrote about the difficult choices faced by developing countries regarding policy toward Foreign Direct Investment (FDI). The dilemma revolves around three often-conflicting objectives. A first objective is the desire for rapid growth; a second is the desire for an equitable distribution of income, and a third objective is the control of one’s own destiny. Four decades later, the design and implementation of policies which balance these objectives without distorting competition and technological development remains a difficult, if not impossible exercise.

Foreign Direct Investment (FDI) is widely considered to be beneficial for the host economy since it can result in positive externalities (spillover effects) through various transmission channels, for instance, transfer of technology, increased competition and imitation effects. This study analyses intra-industry spillover effects of FDI in the pharmaceutical industry in India and the proposal of the Government to regulate FDI in it.

It is to be examined:

- Whether changes in the structure of the pharmaceutical Industry by acquisitions of the Indian Companies by foreign companies can have deleterious effect by reducing competition in the Indian market that could result in increase in price levels of pharmaceuticals in India and less innovation of low cost pharmaceuticals for treating diseases affecting the poor in India.
- Whether acquisition by foreign companies will impact availability of pharmaceuticals in India and increase its dependence on imports
- Whether restraints in the flow of FDI for the purpose of acquisition of Indian Pharmaceutical Companies will unduly constrain the financial resources required for drugs discoveries, keeping in mind the large investments are required for drugs discoveries, including those affecting the poor in India.
- Whether Competition Commission of India is the best institution to supervise the FDI in the Indian Pharmaceutical Industry
The Indian pharmaceutical industry has developed through a range of governmental incentives and, foreign firms that have invested in the industry have additionally contributed to the growth. The results are mixed. Spillover effects are visible in many of the spillover channels from FDI and the regression results show that firms with foreign ownership experience higher productivity levels. However, the correlation between FDI and productivity in domestic firms is insignificant, due to various reasons depending on whether the benefits from FDI are materialized, local firms’ absorptive capability and factors such as the market structure, competitiveness, trade and technological policies. It is in the interest of the state to provide public policies and a sound economic environment to encourage benefit from FDI. Therefore public policies are also taken into consideration in this study.
FOREIGN DIRECT INVESTMENT

Definition of FDI
A foreign investment could be a direct or portfolio investment. A direct investment is an acquisition or construction of physical capital by a firm from one (source) country in another (host) country. The FDI is an investment that involves a long-term relationship and control by a resident entity of one country, in a firm located in a country other than that of the investing firm. There is more involved in the direct investment than only money capital, for instance, managerial or technical guidance. FDI is generally defined as resident firms with at least 10% of foreign participation.

There are numerous ways a multinational can enter a foreign market. Different types of FDI, that involve different levels of control and risks, are the following. Green field investment is when a company establishes a subsidiary in a new country and starts its own production. Greenfield investment involves construction of a new plant, rather than the purchase of an existing plant or firm. This kind of investment involves large risk and set up costs since the foreign firm most likely does not have an existing distribution network, local management skills or enough legislation knowledge. But on the other hand the foreign firm has more control. Brown field investment is FDI that involves the purchase of an existing plant or firm, rather than construction of a new plant. Joint venture is an equity and management partnership between the foreign firm and a local entity in the host market. Many host countries encourage the formation of joint ventures, as a way to build international cooperation, and to secure technology transfer. Typically, the foreign partner contributes financial resources, technology or products and the local partner provides the skills and knowledge required for managing a firm in the host country.

Factors behind FDI- why firms decide to invest abroad

Foreign direct investment has accelerated remarkably in the last decades and many of the major corporations of most developed countries have taken their production of goods to many diverse parts of the world. Investments are most likely to take place where location and comparative advantages are present and FDI will presumably be concentrated to the regions where the

1 UNCTAD, 2002.
2 Samli & Hill, 1998
industry in question is most efficiently performed. In order to compete in foreign markets, multinational companies take advantage of their firm-specific resources, such as technological and marketing expertise. There are several reasons for a firm to undertake foreign direct investment. FDI can be market-seeking (horizontal) or resource-seeking (vertical) FDI. Market-seeking FDI takes place when a MNC invests because of local market size, prospects for market growth, transportation costs and the need to be close to potential customers. The aim for the MNC is often to reduce costs by avoiding tariff and transportation costs and also to be able to meet the local markets’ need better than through export. Resource-seeking FDI seeks comparative advantages such as access to raw material, cheap input and low cost of labour. Furthermore, FDI is a way for firms to avoid trade barriers in order to serve foreign markets and the theoretical aspect of FDI has traditionally regarded trade barriers and tariff jumping. Nonetheless, the tariff jumping perspective has been challenged by the argument of internalizing firm-specific intangible assets, which is described in the next section.

The OLI-Criterion

There are different explanations for why firms choose to produce abroad instead of exporting or entering into a license agreement with a local firm. According to Dunning (1993) there are three conditions, called the OLI-criterion, which must be satisfied for a firm to take on FDI. Ownership: The foreign company must be able to compete with the local producers. This can be achieved through firm-specific assets or skills such as management and technological advantages. Patent and brand name could also give the foreign firm a competitive advantage in the local market. Location: Location advantages, such as natural resources, access to the local market, different factor prices, exchange rates and transportation determine the placement of the investment. Other factors that determine the location of FDI are the host country’s policies regarding FDI, trade barriers, taxes and political stability. It must be more profitable for the firm to produce in a specific location abroad than at home. Internalization: It must be more valuable for the firm to keep its ownership rather than approach foreign markets through licensing or

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selling technology to local entrepreneurs. This could be the case if the firm wants to prevent the technology or assets from being imitated by competitors. Internalization refers to benefits that a firm gains from keeping multiple activities within the same organization. Dunning (1993) claims that all of the three criterions must be fulfilled for a firm to invest in a certain country.

**Investment Incentives**

Dunning’ s OLI- theory is mainly based on characteristics in the host country and the MNCs are, according to this theory, attracted to a specific location by reason of strong economic fundamentals in the host country, for instance pool of skilled labor, infrastructure, political and economic stability. These factors are still relevant for the location of FDI but the importance of *investment incentives* have increased over the years. Governments around the world have lowered entry barriers to encourage more foreign investments and created specific “FDI incentives” to attract foreign capital. Investment incentives can take the form of; tax holidays or lower taxes, financial incentives in the form of grants and loans to the foreign companies, market preference, preferential tariff regime, cutting of red tape, and investment in infrastructure. FDI incentives are very common around the world, both in developed and developing countries. According to UNCTAD (2001) very few countries compete for FDI without subsidies today. A report from 2001 shows that 95% of all changes in national FDI legislation during the 1990s were favourable to foreign investors and most of the changes regarded FDI promotions and different incentives\(^5\). The reason why countries try to attract foreign capital is mainly based on the expectation of positive spillover effects of FDI.

**The spill over effects from FDI**

FDI is often seen as a catalyst for a country’s development and economic growth, which is the reason for attracting FDI to the country. There is extensive economic literature that stresses the importance of FDI and its spillover effects to the host economy. Reasons for the importance of FDI is not only the fact that the foreign investor finances the “hardware” such as investment in new plants and equipment, but FDI can be a major transfer of technology, knowledge and capital for the host industries. With FDI comes financial and managerial resources, access to larger markets, technical assistance and strategic assets, for instance;

\(^5\) UNCTAD, 2001
brand name, which can give the host firms, domestic and international, comparative advantage. Spillover effects may take place when the entry or presence of foreign firms leads to productivity and efficiency benefits in the host country’s local firms. A positive spillover occurs when “local firms benefit from the foreign investment enterprise superior knowledge of product or process technologies or markets, without incurring a cost that exhausts the whole gain from their improved performance.”

**Inter- and intra industry spillover effects**

The spillover effects of foreign firms to the local industries can be divided into two groups; Inter- and intra- industry spillover effects. **Inter- industry (vertical) spillovers** occur through foreign companies’ impact on the local suppliers. Vertical spillovers take place when the foreign firm and a local supplier, in different industries, are engaged in a long- term relationship. Inter- industry spillovers appear through creation of linkages between the foreign company and domestic firms and it is a process that is usually multi- sectorial. Spillovers occur when the local suppliers have to meet the demand from the foreign firm in the form of higher quality, price and delivery standards. Another implication of inter- industry spillover effects is the increased demand by the MNC for local intermediate inputs, thus increasing production possibilities in the host economy. If the foreign firms use intermediate goods, produced by domestic firms, spillover effects may arise when FDI allows domestic suppliers to expand their production and thus reduce their average costs due to increasing returns to scale. Moreover, if there is a technology gap between the foreign and the domestic firms, there is potential for technological improvement in the host economy. The local firms must upgrade their products in order to meet the foreign firm’s demand for advanced products.

**Intra- industry (horizontal) spillovers** result from the presence of MNCs in a particular sector and its influence on the host industry’s competitors. Five transmission channels, through which intra- industry spillover effects might occur, are (i) competition (ii) demonstration and imitation

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7 UN-ECE, 2001, p. 2
8 Smarzynska, 2002
9 Barrios, 2000
effects (iii) transfer of technology and R&D (iv) human capital and labour turnover (v) industrial management.  

**Competition**  
It is likely that the MNC has advantages that overcome potential entry barriers when entering a new market. Advantages, such as financial means, capital, R&D and technological domination, consequently increase the competitive environment in the host economy. Increased competition in an industry forces less efficient domestic firms to take on more efficient production, which can be welfare enhancing for the economy. The superior technology of the foreign firms may stimulate domestic efforts to compete, which may for example lead to new innovations. Since MNCs are likely to have a technological advantage, local firms might be forced to invest in additional human and physical capital, in order to raise productivity and to be able to compete with the MNC. The entry of a foreign affiliate can create or intensify competitive pressure on local firms and stimulate them to use existing resources more efficiently.

If monopoly or oligopoly dominates the industry, the entry of foreign companies can break the inefficient market structure. In addition, if the competitive environment in the host country is high, the MNCs must bring in relatively new and sophisticated technology from their parent firm to keep their market share. Consequently, the scope for further spillover effects is increased. Sjöholm (1999) finds more extensive spillover effects of FDI in industries where the domestic competitive environment in the industry is high. Since the MNC produces in competition with domestic firms, the latter must use their technology more efficiently; consequently elimination of inefficient firms is the result of FDI. However, increased competition could be negative for the domestic firms, if the market is populated with inefficient domestic firms, since the MNCs can sweep them out.

**Demonstration and imitation effects**  
MNCs have advantages due to their possession of proprietary technology, management and marketing skills. Through FDI, these skills are brought into the host economy. Domestic firms can consequently observe the foreign firms’ techniques and later imitate them. Demonstration

10 Blomström et al. 1999  
11 Görg & Strobl, 2001  
12 Taymaz et. al. 2004
and imitation spillover effects represent “learning by watching effect”\(^\text{13}\). Due to the foreign firms’ superior knowledge and technological advantages, spillover effects can occur through adoption of such new technology and knowledge. Technological spillover effects may occur through imitation, reverse engineering and copying of foreign companies’ products or production processes. Knowledge is rarely available on the market but through reversed engineering or hiring foreign employees, with the “proper” skills, it is possible for the local firm to copy products and production processes. Imitation of already existing products might lead to technological progression for the local companies.

Imitation is a primary transmission mechanism of FDI to local firms and especially reverse engineering for technology transfer of new products and processes in a north–south perspective. Any upgrading of local technology deriving from imitation could result in productivity spillover from foreign to the local firms \(^\text{14}\).

**Transfer of technology and R&D**

Technology can be characterized as “technical knowledge applied in the production of any article of commerce”\(^\text{15}\). Many standard models of MNCs assume that they possess knowledge assets, for instance patents, trademarks and exclusive technology. MNCs are usually Research and Development (R&D) and capital intensive; hence a potential source of intra-industry spillover is the transfer of production and process technology from MNCs to the domestic companies. The foreign firms make the domestic players aware of the existence of the technology and the MNCs are likely to speed up the domestic firms’ technology. Enhancement in technology enables firms to increase productivity and build competitiveness in new areas\(^\text{16}\).

Technology and productivity gaps between the foreign and local firm may stimulate spillover effects. If a technology gap exists we should expect to find some differences in productivity and innovations between foreign owned and domestic firms. If the local firm is less productive than the foreign firm, there is scope for it to catch up, by imitating the technology of foreign leaders. Blomström (1986) found that multinationals acted as a catalyst for the Mexican manufacturing sector and that there was productivity convergence between Mexican and American firms in

\(^{13}\) Blomström et. al. 1999

\(^{14}\) Görg & Greenaway, 2001

\(^{15}\) Naravana, 1984, p. 87

\(^{16}\) Mansfield & Romeo, 1980
several industries. However, there is a risk that the MNCs’ advanced technology is beyond the local firm’s absorptive capacity, which could lead to adverse consequences for the domestic firms’ market position.\(^\text{17}\)

Another activity, that could stimulate spillover effects and technology transfer, is the R&D performance that the MNC may undertake in the host country. The MNCs are often very R&D intensive, but generally concentrate most of their research activities in the parent affiliate, which limits the scope of spillover effects. The focus of R&D that is carried out in the foreign affiliate is often a modification of the parent technology, so it suits the foreign market.\(^\text{18}\) The spillover effects from R&D are therefore usually generated outside the host country and brought in through the FDI.

**Negative spillover effects**

Despite the theoretical assumptions of positive spillover effects, the empirical results of earlier studies of FDI impact on the productivity of domestic firms are mixed, i.e. positive, negative and insignificant results.\(^\text{19}\) Aitken & Harrison (1999) argue that FDI can have negative effects on the domestic firms’ productivity, which may be large enough to offset the positive impact from FDI. The so-called “market stealing effect” refers to when foreign firms enter a host economy and their technology advantages take over the domestic market shares. The MNCs’ advantages draw demand away from the domestic firms’ products; hence the domestic firms’ productivity decreases. Examples of studies that show negative spillover effects are Aitken & Harrison (1999) and Haddad & Harrison (1993).

There are several explanations for the mixed results of earlier studies of spillover effects, such as different measuring techniques and unreliable data used in the studies.\(^\text{20}\) The varied results are also argued to depend on characteristics of the host country and the investing firms. Explanations such as “absorptive capability” of the host economy, domestic market competition, ownership structure of foreign firms and technology gap between foreign and domestic firms in the industry can explain the different outcomes. Absorptive capability refers to the fact that FDI may be more

\(^{17}\) UN-ECE, 2001

\(^{18}\) Blomström et al. 1999

\(^{19}\) Görg & Greenway, 2001

\(^{20}\) Görg & Strobl, 2001
beneficial for an industry if the domestic firms have a minimum level of technological development and human capital\textsuperscript{21}.

There are divergent views on the impact of performance requirements. While some experts consider them as essential in FDI policy, others argue that their impact on investments is costly and can limit the inflow of FDI; consequently becoming counter productive. With the aim of creating linkages from FDI within the economy, proponents of performance requirements argue that competition is a more effective way. Through local competition, domestic and foreign firms will automatically link up through alliances, and the industry will develop better without governmental interventions\textsuperscript{22}.

\textsuperscript{21} Blomström & Kokko, 2003
\textsuperscript{22} UNCTAD, 2003
THE INDIAN PHARMACEUTICAL INDUSTRY IN A HISTORICAL PERSPECTIVE

“The Indian pharmaceutical industry is a success story providing employment for millions and ensuring that essential drugs at affordable prices are available to the vast population of this sub-continent.”

Richard Gerster

This chapter focuses on the Indian pharmaceutical industry and primarily on its evolution. The history of the industry is important in order to understand the growth and the impact foreign firms have had on the industry. The chapter begins with an introduction to the pharmaceutical industry from a global perspective and continues with the history and development of the Indian pharmaceutical industry, which can be divided into three time periods.

Due to the pharmaceutical industry’s capital and know-how intensity, most of the world’s production is located in the developed countries. India is one of the few developing countries with a large production base in pharmaceutical products. India’s trade in pharmaceutical products has increased a lot since the liberalization reforms and it has comparative advantages in trade with pharmaceutical products, both bulk drugs and formulations. The Indian pharmaceutical industry ranks very high among developing countries, in terms of technology and quality, and is today in the front rank of India’s science based industries.

The growth of the Indian pharmaceutical industry has been remarkable. The industry is today the fourth largest globally, in terms of volume, and 13th largest in terms of value. The industry accounts for 8% of the global sales in volume but in terms of value it is barely 1%. The role of the Indian pharmaceutical industry in the international market today is as a supplier of good quality, low cost generic bulk and formulation.

Potential growth of the Indian pharmaceutical industry is great. Nearly 65% of India’s population does not enjoy comprehensive access to quality healthcare today. A large share of the population

23 DIPP, 2005
24 ICRA, 2004
use alternative medicine and per capita consumption of drugs in India is one of the lowest in the world\textsuperscript{25}. 

*Multinationals* are, in addition to the public sector, a part of India’s pharmaceutical foundation. Foreign companies entered the Indian market merely as trading companies with small investments. The new industrial policies emphasized the importance of foreign capital and industrial know-how. The Indian government carried out liberal FDI policies and incentives to invite foreign firms to start manufacturing facilities in order to get an inflow of know-how in the sector. The leading pharmaceutical companies from the West came to India and established manufacturing facilities. Subsequently, the multinationals brought in technology and international manufacturing practices\textsuperscript{26}. Domestic firms were encouraged to tie up with foreign firms, with participation in capital, and there were collaboration agreements in the private sector. The foreign firm Hoechst established a research centre, which enhanced basic research in India\textsuperscript{27}. During this time product patent laws, which were favourable for the MNCs, were in force. India was attractive to foreign firms mainly due to its large market and increasing demand for drugs. At that time there was lack of competition in the Indian pharmaceutical industry and the MNCs did well in India. They had good knowledge and technology to develop antibiotics and synthetic drugs and advantage of their financial assets and management abilities. Consumer preference for foreign world-wide known drugs was also an advantage for the MNCs in India. They were aggressive in marketing and managed to create a market for themselves in branded products. The foreign companies had, more or less, a monopoly in the Indian pharmaceutical market at this time.

Supported by the IMF and the World Bank, India started to liberalize its economy in 1991. The liberalization of the Indian economy affected the pharmaceutical industry in several ways. The public units that had a production monopoly in certain drugs were opened up for competition and privatized\textsuperscript{28}. Also, the requirement for a certain ratio in bulk drug production was removed and equity share and approvals of FDI in the industry were relaxed. To improve the attractiveness of

\begin{itemize}
\item \textsuperscript{25} OPPI, 2005
\item \textsuperscript{26} ICRA, 2004
\item \textsuperscript{27} Naravana, 1984
\item \textsuperscript{28} Aggarwal, 2004
\end{itemize}
the industry the government changed the DPCO and reduced the number of drugs under price control from 347 in 1970 to 74 in 1995\textsuperscript{29}.

**A Snapshot**

- Net Worth of the Indian Pharmaceutical Industry is 8 Billion Dollars.
- Growth Rate of 8-9% PA.
- 4th in the World in terms of Volume of Drug Output
- Exports to nearly 212 countries @ USD 4795.33 million (2005-06)
- Has an important role to play in promoting public health and Right to Health.
- Highly technology and knowledge intensive
- There is no single market. The market is divided into therapeutic segments. i.e. vitamins, respiratory disorders, cardio ailments, antifungal, antibiotics etc…
- No consumer choice. The consumer is dependent on the information provided by the pharmacist and the doctor.

**Competition Overview**

Competition is mainly from the domestic manufacturers and imports from China because of the low manufacturing cost. With the new patent regulations the industry expects to see a major structural shift with the entry of foreign pharmaceutical manufacturers.

There are five government-owned companies the Indian public sector. These companies are the Indian Drugs and Pharmaceuticals, Hindustan Antibiotics Limited, Bengal Chemicals and Pharmaceuticals Limited, Bengal Immunity Limited and Smith Stanistreet Pharmaceuticals Limited. Some of the major Indian private companies are Alembic Chemicals, Aurobindo Pharma, Ambalal Sharabhai Limited, Cadila Healthcare, Cipla, Dr. Reddy’s, IPCA Laboratories, Jagsonpal Pharma, J.B. Chemicals, Kopran, Lupin Labs, Lyka Labs, Nicholas Piramal, Ranbaxy Labs, Matrix Laboratories, Orchid Chemical and Pharmaceuticals, Sun Pharmaceuticals, Ranbaxy Laboratories, Torrent Pharma, TTK Healthcare, Unichem Labs, and Wockhardt.

The foreign companies in India include Abott India, Astra Zeneca India, Aventis Pharma India, Burrough-Wellcome, Glaxo SmithKline, Merck India, Novartis, Pfizer Limited, and Wyeth Ledele India.

India also exports pharmaceuticals to numerous countries around the world, including to the U.S, Germany, France, Russia and UK.

\textsuperscript{29} Department of Chemicals, 2005
FDI IN THE INDIAN PHARMACEUTICAL INDUSTRY

The inflow of foreign direct investments into India has increased since the liberalization reform started. In the following chapter the FDI in the pharmaceutical industry is reviewed. An overview of the FDI policies in the pharmaceutical industry and the reasons why MNCs invest in India are given.

Policies regarding FDI in the pharmaceutical sector

The foreign pharmaceutical firms in India have met a restrictive environment. There used to be performance requirements for the foreign firms investing in the Indian pharmaceutical industry, in order create linkages between foreign and domestic firms. A summary of which performance requirements have been imposed on foreign firms over the years in India is found in table

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<tr>
<td>Export</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Equity share</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>R&amp;D</td>
<td>No</td>
<td>Yes</td>
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<tr>
<td>Technology transfer</td>
<td>No</td>
<td>Yes</td>
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As one can see, all the performance requirements for foreign firms, except export and employment, have been in force during the development of the Indian pharmaceutical industry. The requirements were predominantly in place during the “second phase” in the history of the Indian pharmaceutical industry, when the industry was most protective. The 1978 Drug policy was intended to use the foreign firms’ strength and to generate linkages within the industry and support the domestic industry.
Export or employment/ training requirements for foreign pharmaceutical firms have not been imposed in India. Nevertheless, Joint venture and equity ownership requirements were in force during the first and second phase. Through not allowing 100% foreign equity, the local firms have a better chance to share the knowledge and inputs from the foreign firm. In India domestic equity requirements have helped to promote the formation of joint ventures and generate externalities in the form of local learning and absorption of knowledge brought in by the foreign partners. For instance, Ranbaxy and Eli Lilly formed a joint venture because of the requirement. Today, FDI up to 100% foreign ownership is allowed in the pharmaceutical industry through the automatic approval route.

R&D requirements have been a condition for foreign firms in India. For instance, it was compulsory for foreign pharmaceutical companies to set up R&D facilities and spend at least 4 percent on R&D of their turnover annually, if their turnover was more than Rs. 5 Crores (Dhar & Rao, 2002). To enter into long-term consultancy agreements with relevant R&D institution in the country, within 2 years of FDI approval, was also an option. Furthermore, technology transfer is one of the main objectives for host countries attracting FDI. The Government of India encouraged technology transfer but did not adopt any requirements. However, foreign firms faced constraints regarding the import of technology.

Today, there are no performance requirements in the pharmaceutical industry. The Foreign Direct Investment policy in India is liberalized and the government tries to get less involved in the private sector and leave it to market forces. Policy initiatives that have been imposed to liberalize the economy in respect of FDI are for example; industrial decontrol, simplifications of investment procedures and commitment to safeguarding intellectual property rights.

There are many factors that are important to MNCs when deciding where to locate new affiliates and production. In a high technology industry, such as the pharmaceutical, factors such as; skilled/ semi skilled labour, well- developed local supply chains, well functioning infrastructure and knowledge producing institutions are important for a firm to consider. Some of these factors are reasons why pharmaceutical multinationals have invested in India.

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30 Gulati, 2005-10-11
31 SIA, 2004
The FDI in the Indian pharmaceutical industry is mainly market-seeking. India’s advantage for MNCs in the pharmaceutical industry is, first of all, the large domestic market with a 1.1 billion population and an annual increase of 2.2%.\(^{32}\) India’s large population and wide disease pattern make the country attractive for pharmaceutical firms. Relatively cheap manpower and skilled labour are other factors that attract foreign investors. India has an exceptional advantage in pharmaceuticals due to its good human resources and highly skilled workforce. English is widely spoken, which makes communication easy for foreign investors. The production of pharmaceuticals is also relatively cheap in India and there is a strong production base in the country. It is easy to get good quality bulk drugs, which is attractive for foreign firms. Because of India’s focus on reverse engineering and development of production processes, it has high technical competence in production in the pharmaceutical industry, which makes its industry attractive for foreign investors. The industry is also very highly competitive among suppliers, which gives the MNCs a good bargaining position. India has many advantages for foreign investors and consequently, the country has future potential to become an attractive destination for outsourcing in drug discovery and clinical research.

Production costs have risen in the pharmaceutical industry by reason of increased complexity of the chemical structure of drugs. Outsourcing production or research activities can lead to cost reduction for the company and many foreign pharmaceutical companies outsource parts or their entire production in India. Labour unions, rigid labour laws, and a lot of red tape in India make outsourcing more attractive to foreign companies than having their own manufacturing units. Today, GlaxoSmithKline outsources 70% of its production and Novartis 100% of its production.\(^{15}\) Pfizer and Organon have sold out some or all of their manufacturing units in India, since they find it more profitable to outsource their production to local manufacturers instead of producing in their own factories. Outsourcing may lead to reduction in the investment required and offer better financial returns. According to the MNCs interviewed, it is more economically efficient to use contract manufacturers since the plant is already set up, and the firms do not have to deal with strikes and Indian labour laws.

Regarding R&D in the Indian pharmaceutical industry, the investments are very low, compared to global expenditures. The Indian industry has developed through reverse engineering and

\(^{32}\) STC, 2004
process technologies, rather than innovation of new products. One of the obstacles for Indian firms in product innovation is the large financial means required. However, the difference between MNCs and domestic firms, in terms of R&D in India, is small. In fact, today the large domestic players invest more in R&D than the MNCs in India. The reason the MNCs perform limited R&D is again the weak patent regime.

The average level of R&D in domestic and foreign firms in India was similar in 1990, but in the last decade Indian companies have started to invest more in R&D. The domestic firms have increased their expenditures on R&D more than the MNCs in India since 1990. The explanation is the transition to the new patent regime in 2005

**Pharmaceutical Mergers and Acquisitions – India2010**

- Right now the market is highly fragmented
- Mergers and acquisitions could lead to consolidation of market shares
  - June – Acquisition of 51% stake in Ranbaxy by Daiichi Sankyo Company Ltd Japan
    - Deal valued at Rs.19,780 crores.
    - Ranbaxy valued at 8.5 Billion Dollars
    - Ranbaxy to become an independent generic arm of the company
    - Daiichi primarily looked at Ranbaxy’s marketing network in 60 countries as opposed to its (21 countries)
    - Ranbaxy to benefit from Daiichi’s research strengths

Since 2006, as many as six big Indian pharma companies have been taken over by foreign firms. About $4.73 billion or 50 percent of the recorded FDI in the sector since the year 2000 has been in the form of mergers and acquisitions. In the year 2006, Matrix Lab was sold to the US-based company Mylan. In 2008, Dabur Pharma was bought by Singapore-based Fresenius Kabi. Again in the same year, Ranbaxy was taken over by the Japanese company, Diachii Sankyo. The year 2009 witnessed two major deals in which Shantha Biotech was taken over by the French major Sanofi Aventis and the US-based company Hospira took over Orchid Chemicals. The latest example is of Piramal Healthcare, which was bought in the year 2010 by the US multinational, Abbot Laboratories.

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33 Competition law and Pharmaceutical Industry by Adithya krisha Chintapanti, Center for Trade and development
Summary
India has many attractions for FDI, such as; skilled labour, large population and a strong production base in the pharmaceutical industry. The pharmaceutical industry has been the eighth largest sector in India attracting FDI since 1991. Despite liberalization and deregulation of the pharmaceutical industry, foreign capital in the industry is still quite low. The majority of the global pharmaceutical firms have invested in India, but due to the weak patent regime, price control and rigid labour laws, the firms tend to outsource a large part of their production and do not invest much in R&D. The government of India wants to increase the FDI inflow into the industry, and they hope to attract more foreign capital with further liberalization of policies regarding the pharmaceutical industry\textsuperscript{34}. The Indian government implemented performance requirements for foreign pharmaceutical firms in order to create linkages and spillover effects between the foreign firms and the host economy. However, today there are no performance requirements for foreign firms that invest in the pharmaceutical industry in India.

\textsuperscript{34} DIPP, 2005
FDI IN PHARMACEUTICAL INDUSTRY AND IT’s IMPACT ON COMPETITION

Competition
Foreign firms have been a part of the Indian pharmaceutical industry since its initial stage. When the first MNCs entered the Indian market they basically had a monopoly in the industry, as the domestic industry was not competent enough to compete with the MNCs and thus there were no spillover effects in terms of increased competition. Today, the domestic industry is well developed, which means that MNCs and the local firms compete at the same level. In 1992, thirteen companies of the top twenty had foreign origins, but today the number of MNCs at the top has decreased because of lower profit margins and increased competition from domestic firms. The presence of MNCs in India has a large impact on the competitive environment in the Indian pharmaceutical industry and stimulates the domestic firms to upgrade their technology and investments in marketing.

The business environment in the Indian pharmaceutical market is today highly competitive with a large number of players. Features such as costs, research orientation, product portfolio, production capability and marketing and distribution network are important factors for a firm to succeed and be able to compete effectively in the pharmaceutical industry. The MNCs in India are characterized by advantage in many of these factors, while their domestic competitors have an advantage in production capacities and costs. Since the foreign firms do not have cost advantage in production, they invest large sums in marketing and fieldwork to promote drugs. Today the domestic companies seem to have adopted the MNCs’ marketing expertise and strategies to be able to compete. The domestic firms are more or less forced to try to keep up with the MNCs’ marketing abilities and the local firm’s increased market share indicates they have been doing well.

With the introduction of the product patent regime in 2005, more research-based pharmaceutical companies are expected to establish their presence in India. Many of the domestic firms are strong enough to face increased competition in the new setting, but the firm must have reached a certain level to be able to compete with the foreign companies and also with the largest domestic firms.

35 Felker et. al. 1997
The enhanced competitive environment in the new patent regime may be difficult for the small-scale producers. Many of the small-scale producers are lacking production/product quality and many are also inefficient. According to one small-scale producer, the government support, in terms of help with up-gradation, is not enough. It will be tough for the small firms to handle the competition and transition to the new patent regime. There is therefore risk of a “market stealing effect”, negative spillovers, with increased pressure from the new scenario in the Indian pharmaceutical industry. It is likely that many small-scale firms have to lower their production or shut down since they can not handle the competition. Nevertheless, spillover effects from competition lead to the reduction of inefficient firms, and in the short term unproductive firms are likely to be swept off the market. On the other hand, in the long term, the industry is likely to develop because of better allocation of resources.

Acquisition of the only generic companies with the wherewithal to manufacture variants could have adverse implications for availability of off patent drugs. It may Have Adverse Implications for Specific Therapeutic Areas. Drugs worth more than $90 billion are going off patent in the near future. It could lead to perpetual extension of the term of the patent because of absence of competitors.36

Availability of Drugs and Price Rise
There is a general belief that MNCs will cause prices of medicines to go up and will reduce availability of generics in the market. It is also believed that there may be a concerted strategy by foreign companies to take over the Indian drug industry and divert its capacity towards Western markets thus depriving Indian consumers of low cost medicines. On the other hand there is a well substantiated view that MNSs recognize that the future growth in the global drug market will be far more in countries such as China, India, and other developing countries, and therefore their strategies are to enter and sell more in these markets, which will have a positive impact on the competition in the pharmaceutical Industry. The attractiveness of the local market will grow substantially with social and economic progress and inevitable increase in public expenditure on

36 Competition law and Pharmaceutical Industry by Adithya krisha Chintapanti, Center for Trade and development
health. India is also seen as an attractive base for manufacturing of generics for exports both by multinational and Indian Companies. Acquisitions of other companies already established in the market is a universal business strategy in all industries and in all countries, to save time and also ensure more surety of success. Therefore the recent acquisitions of Indian pharma companies by MNCs could as well be an expression, as some evidence suggests, of these foreign companies to grow their business by investing more India to produce and sell more in India itself. This could be in India’s interest, by bringing in more investments and more technologies into our health sector and may not have an adverse effect on competition.

The Department of Pharmaceuticals has analysed data regarding prices and availability of medicines over the past few years and also exports and imports. The data does not substantiate that acquisitions so far have led to stoppage of nationally relevant drugs. Also a relationship between acquisition and increase in prices is not seen\(^{37}\). It is of course to be recognized that acquisitions are recent and more definitive trends will become evident over time.

Indian Pharmaceutical Industry is an open industry. Therefore the chances of MNCs having a monopoly over it are minimum. If the multinationals take over the generic goods, the present indigenous pharma industry of India is well equipped to come up with more generic drugs. The Government can moreover try alternative policies such as public procurement of drugs from the indigenous companies to ensure the availability of these goods. Where there is a demand for generic goods in a country like India, it is easy to find producers to match that demand.

The prices of essential drugs are anyways controlled by the Government of India through Drugs Under Price Control, DPCO, 1995. Seventy Six essential goods are included under Drugs under Price Control, DPCO,1995. National Pharmaceutical Pricing Authority is also in place to act as a watch dog over the pricing of drugs in India.

It must also be recognized that monopolistic situations and unreasonable upward pressure on prices, can also result from strategies of acquisitions, cartelization, and unfair trade practices of domestic players within the Indian market even if there were no foreign companies. Further, Indian industry itself may diversify investment into other areas as the pressure on drug

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\(^{37}\) [http://pharmaceuticals.gov.in/](http://pharmaceuticals.gov.in/)
innovation increases with the growing stringency in regulatory requirements. Therefore a properly equipped institutional mechanism is required to handle this issue.

While addressing the issues relating to FDI and its adverse effect on competition it must be taken care that Government does not come up with very stringent measures that may restrict FDI and thus deprive India of its spillovers.

Statistics: Data analysis by Department of Pharmaceutical

1. Escalation in Drug Prices

DoP has conducted a price analysis of the drugs for the period May 2009-2011 as per following categories

a. 7 top domestic companies: Cipla, Sun, Mankind, Alkem, Lupin, Zydus Cadilla and Intas
b. 7 top MNCs: Abbott, GSK, Pfizer, Sanofi Aventis, Novartis, MSD and Merck
c. 7 Major Indian Companies acquired by MNCs: Ranbaxy, Ranbaxy Global CHC, orchid, Shanta, Paras, Dabur and Piramal.

Above analysis reveals the following-

a. Out of a total of 8348 packs, there has been no change in prices for 67.3% of the packs.
   Only 6.7% packs had price increase up to 5% and 1.8% had price increase more than 15%
b. Out of total of 3503 packs, there has been no change in prices for 66.7% of the packs.
   Only 7.6% packs had price increase up to 5% and 5.1% had price increase more than 15%
c. Out of a total of 2035 packs, there has been no change in price for 70.8% of the packs.
   Only 6.8% packs had increase up to 5% and 2.9% had price increase more than 15%.

As regards the general trend of price increase in the domestic market for all companies and all packs as estimated by IMS, it is to be emphasized that out of a total wholesale traded market size of Rs. 48,239 crores comprising 60,498 medicine packs covering 507 pharma companies, the situation in respect of price rise is as below:
<table>
<thead>
<tr>
<th>Percentage</th>
<th>2008-09</th>
<th>2009-10</th>
<th>2010-11</th>
</tr>
</thead>
<tbody>
<tr>
<td>% No. of packs whose prices have increased</td>
<td>0.07</td>
<td>1.99</td>
<td>0.09</td>
</tr>
<tr>
<td>% No. of packs whose prices have decreased</td>
<td>0.01</td>
<td>1.32</td>
<td>0.06</td>
</tr>
<tr>
<td>% No. of packs whose prices are unchanged</td>
<td>99.93</td>
<td>96.69</td>
<td>99.85</td>
</tr>
<tr>
<td>% No. of packs whose prices have increased by 20% and fulfilling DPCO criteria*</td>
<td>0.28</td>
<td>0.035</td>
<td>0.03</td>
</tr>
<tr>
<td>% No. of packs whose prices have increased by 10% and fulfilling DPCO criteria*</td>
<td>0.84</td>
<td>0.18</td>
<td>0.16</td>
</tr>
</tbody>
</table>

Note: *each year as estimated in the month of April of the year concerned by IMS

**Conclusion**

Thus it may be seen that the trend that in prices for all the three categories is similar so far and no conclusion can be drawn to support the hypothesis that acquisition by MNCs of Indian origin companies has resulted in price increase.

**2. Availability of Drugs:**

- A trend analysis of the total number of medicine packs available in the domestic market in the last two years shows an increase of 4.3% between March 2009 and March 2010 and 1.4% between March 2010 and March 2011. The overall increase has been 5.8% between March 2009 and March 2011.
- A trend analysis of the total number of new drugs/formulations introduced in the domestic market since May 2009 as per IMS for the 3 categories of companies mentioned in issue No.1 above reveals that the total number of new drugs/formulations for each category are:
  A. 1439
  B. 512
  C. 341
**Conclusion**

Thus there has been increase in the number of medicines packs in the last years as against perceived decrease in the number of medicines by the Health Department. This is further supported by the fact the number of new drugs/formulations introduced by the 3 categories discussed above.

Specific data may need to be provided by the Health Department in respect of essential medicines which the Health Department deems necessary for national needs. This is important in the context of possible need of compulsory license provision under TRIPS. However, the existing data does not support the proposition that there has been, or there is, a trend towards decreased availability of medicines on account of acquisition of Indian companies by MNCs.

**FDI SPILLOVERS**

**Imitation and demonstration effects**

Foreign firms in India have “unwillingly” contributed to the industry’s development through domestic firms imitating their products. Imitation of already existing products has led to know-how adoption and technological development for the local Indian companies. Consequently, the spillover effects from imitation of foreign firms’ technology and knowledge seem to have been large in the Indian pharmaceutical industry.

The Indian pharmaceutical industry would not have been able to develop as fast if firms were not allowed to make copies of already existing molecules and drugs. The average cost of developing a new drug for the international market is high and large investments are required for the process. It is much cheaper and less time-consuming to develop new processes and produce already existing products and for India, with limited resources, the industry could develop because of the production of generic drugs. The loss of knowledge to Indian imitators was a cost for the MNCs but nonetheless most of the foreign firms decided to stay in India by reasons of their large sales in the Indian market. The MNCs had at the time, and still have, strong brand names in India and the low costs and pool of high skilled labour made it valuable to stay.
Transfer of Technology

Spillover effects, in terms of technology transfer, can be created if the MNCs use more advanced technology in their production processes than domestic firms. Thus, technology and productivity gaps between the foreign and local firm may stimulate spillover effects. If the local firm is less productive than the foreign firm there is scope for it to catch up. Technology in the pharmaceutical industry is often very complex and the need for upgrading the technology is large due to the rapid pace of new drug discovery and strict requirements of safety and efficiency. Foreign pharmaceutical affiliates in India receive up to date technology from their parent firm, both in managerial practices and in manufacturing facilities, which could stimulate spillover effects.

Considering the pharmaceutical industry’s high-technology intensity, there seems to be limited technology transfer taking place in India. The MNCs in India made technology available to the domestic industry at an early stage, but today technology transfer is rather limited. Since the MNCs do not conduct much R&D in India, the domestic firms’ (the larger ones) technology is equally developed as the MNCs. Nevertheless, there might be more technology transfer in the future when the IPRs are protected. According to Pfizer, newer technology will most likely become available to domestic firms when there is a strong patent regime, mainly through collaborations between MNCs and domestic firms. It is possible that under the new patent laws, MNCs will start to outsource even patented drugs in India; consequently there will be larger scope for technology transfer spillovers in the future.

Research and Development

R&D centres in the Indian pharmaceutical industry have begun to emerge, which increases employment opportunities and also reverses the brain drain from India. The R&D centres attract Indian scientists who earlier migrated to developed countries to find suitable work opportunities. With the new patent regime and enhanced work pool of skilled labour, it is very likely that MNCs will begin innovative research in India in the future. R&D activity is very competitive, which can benefit the domestic industry in terms of increased focus on innovation and improvement. If the foreign companies start to develop R&D units in India, the competition is likely to increase among the players in the industry. Further spillover effects in terms of

38 Naravana, 1984
39 D'Souza, 2005-12-20
competition in R&D activities will possibly be generated in the future. As more domestic companies engage in various parts of the R&D, the knowledge gap between the firms will decrease and the absorption capability of spillover effects increase.

**Labour training and human capital**

Well trained employees can be a source of a firm’s productivity gain when the resources are used more efficiently. Training and development of employees across all levels is a key investment area for many of the MNCs. The aim of investment in training is to make each employee highly productive. The pharmaceutical MNCs in India have collectively thousands of employees, who enroll in training programs. Thus, there seem to be spillover effects generated in terms human capital in the Indian pharmaceutical industry.

**Industrial management**

The local industry can benefit from FDI through the superior industrial management skills that the MNCs possess. Because of the threat of market loss, foreign companies can raise managerial incentives in host-country enterprises. A well functioning industrial management is very important for a firm’s growth and efficient management can increase the productivity of the firm significantly. The lack of marketing skills forces Indian firms to produce for the domestic market instead of expanding into the global market. It can therefore be argued that spillover effects in terms of marketing infrastructure are especially important for firms that want to expand internationally.

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40 Bhujle, 2005-12-06

41 Dunning, 1970
THE COMPETITION COMMISION OF INDIA AND FDI IN PHARMACEUTICAL INDUSTRY

In the previous chapter it was established that a well equipped institutional mechanism is required to deal with the issue of FDI in pharmaceutical industry. This system must be sensitive to public interest, evidence based, supported by strong processes and consistent in its assessment processes and judgments over time. The two possible mechanisms that are readily available are the Foreign Investment Promotion Board (FIPPB) and the Competition commission of India (CCI).

FIPPB
The Foreign Investment Promotion Board (FIPB) is a government body that offers a single window clearance for proposals on Foreign Direct Investment (FDI) in India that are not allowed access through the automatic route. FIPPB comprises of Secretaries drawn from different ministries with Secretary, Department of Economic Affairs, MoF in the chair. This inter-ministerial body examines and discusses proposals for foreign investments in the country for sectors with caps, sources and instruments that require approval under the extant FDI Policy on a regular basis. The Minister of Finance, considers the recommendations of the FIPPB on proposals for foreign investment up to ₹1200 crore. Proposals involving foreign investment of more than ₹ 1200 crore require the approval of the Cabinet Committee on Economic Affairs (CCEA). FIPB is mandated to play an important role in the administration and implementation of the Government’s FDI policy. It has a strong record of actively encouraging the flow of FDI into the country through speedy and transparent processing of applications, and providing on-line clarification. In case of ambiguity or a conflict of interpretation, the FIPB has always stepped in with an investor-friendly approach.42

Functions of FIPPB

- To quickly approve the foreign investment proposals.
- To review the foreign direct investment polices and to communicate with other agencies such as the Administrative Ministries in order to set up guidelines that are transparent and which encourage FDI into the various sectors of the country.
- To look over the implementation of the various proposals that have been approved by it.

42 http://www.fipbindia.com/
• To take up such activities that encourages FDI into the country such as establishing contact with international companies and also inviting them to invest in India.
• To communicate with government, non-government and Industry Bodies in order to increase the flow of foreign direct investment into the country.
• To communicate with the Foreign Investment Promotion Council that has been set up in the Industry Ministry.
• To identify the various sectors that requires foreign direct investment.
• To take up all other activities that help in increasing the flow of foreign direct investment into the country.

CCI

**Competition Commission of India** is a body of the Government of India responsible for enforcing The Competition Act, 2002 throughout India and to prevent activities that have an adverse effect on competition in India. It was established on 14 October, 2003.

The Competition Act is an Act to provide, keeping in view of the economic development of the country, for the establishment of a Commission to prevent practices having adverse effect on competition, to promote and sustain competition in markets, to protect the interests of consumers and to ensure freedom of trade carried on by other participants in markets, in India, and for matters connected therewith or incidental thereto.  

The objectives of Competition Law have been further highlighted in a recent judgment delivered by Hon’ble Supreme Court as:

"The main objective of competition law is to promote economic efficiency using competition as one of the means of assisting the creation of market responsive to consumer preferences. The advantages of perfect competition are three-fold: allocative efficiency, which ensures the effective allocation of resources, productive efficiency, which ensures that costs of production are kept at a minimum and dynamic efficiency, which promotes innovative practices".

To achieve its objectives, the Competition Commission of India endeavors to do the following:

- Make the markets work for the benefit and welfare of consumers.

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43 [www.cci.gov.in]
44 in Civil Appeal No. 7999 of 2010 pronounced on 9th September, 2010
• Ensure fair and healthy competition in economic activities in the country for faster and inclusive growth and development of economy.

• Implement competition policies with an aim to effectuate the most efficient utilization of economic resources.

• Develop and nurture effective relations and interactions with sectoral regulators to ensure smooth alignment of sectoral regulatory laws in tandem with the competition law.

• Effectively carry out competition advocacy and spread the information on benefits of competition among all stakeholders to establish and nurture competition culture in Indian economy.

Regulation of Combinations by CCI
The Act prohibits any person or enterprise from entering into a combination which could cause or is likely to cause an appreciable adverse effect on competition in India.\textsuperscript{45} The Commission is empowered to declare such combinations as void. The commission can look into the merger or amalgamation upon receiving a notice from the parties or a statutory authority.

Parameters for the Commission to Investigate Combinations

• Barriers to entry into the market\textsuperscript{46}

• Extent to which substitutes are available or are likely to be available in the market.\textsuperscript{47}

• Likelihood that the combination would result in the removal of a vigorous and effective competition or competitors in the market.\textsuperscript{48}

• Implications for the nature and extent of innovation.\textsuperscript{49}

The commission can either approve the said combination or reject the same. In the alternative the Commission can also propose modifications to the terms of the combination.

\textsuperscript{45} Sec.6 (1) of the Competition Act, 2002
\textsuperscript{46} Section 20.4.b. of the Competition Act, 2002
\textsuperscript{47} Section 20.4.g of the Competition Act, 2002
\textsuperscript{48} Section 20.4.i. of the Competition Act, 2002
\textsuperscript{49} Section 20.4.l. of the Competition Act, 2002
Factors in the favor of CCI

- In the past, until the passage of the Competition Act and creation of the Competition Commission, control of the sizes and structures of companies in an industry, to ensure a healthy structure of companies in an industry, to ensure a healthy structure of the industry, was sought to be managed by administrative decisions of ministries and the FIPPB route. This approach had the connotations of the ‘license raj’ along with the impression of arbitrariness of government decisions. On the other hand, ‘competition’ management by competition commissions and competition acts is accepted by even the freest market countries, including the USA as the right approach to regulate activities of players in the market to ensure that the structure of the industry is not distorted against the consumer’s interests. If India adopts these instruments of competition management, it cannot be accused of ‘going back’ on reforms and discouraging foreign investment.

- The Competition Commission of India operates within a well defined structure, providing legal certainty and transparency to the parties, who have full opportunity to exercise their rights and strong legal protection against any arbitrary decision, with clearly defined appellate processes.

- In its inquiry into cases of mergers and acquisitions, it takes into account the entire gamut of relevant issues, including those relating to the specific market, interests of consumer, likely impact on prices and availability of relevant products/ substitutes, innovation, competitiveness, contribution to economic development etc., and the likely effect of the proposed M &A on competition market.

- The Competition Act 2002 empowers the Commission to evaluate all aspect of the proposed deal such as reduction of capacities for production or R&D and market distorting issues related to ownership of IPR. It can reject a proposal or approve it with modifications in the final reasoned order, which is required to be delivered within time limits prescribed in the Act/Regulation (30 days for prima facie determination, and 180 days in case further investigation is required). In prescribing the modifications in its order, the Commission can require the parties to make structural changes in either of, or both, the acquiring and acquired entities. Further, the Commission’s order can include behavioral/ conduct remedies also regarding capacities, IPR issues, etc.
The Competition Commission of India has already designed internal processes for specifically consulting and obtaining requisite data and expert advice from appropriate sources, including the concerned ministries/ departments of the government and the sectoral regulators, in line with the provisions of the Competition Act, 2002 which duly enable and empower CCI for this purpose. This structure has in-built systems for consultation with designated persons/ cells in these organizations.

Factors Against CCI

- The role and powers of the CCI have been notified very recently. The capacities of the CCI would need to be strengthened if it has to act as a gate-keeping mechanism for acquisitions in the drugs and pharmaceuticals-sector.
- While laws may be sophisticated, the ultimate test of their efficacy lies in the implementation. Moreover, at this stage, no empirical evidence is available which would enable an analysis of the efficacy of the institution with respect to public interest issues.
- The issue of threshold in the Competition Act is critical. Most pharmaceutical companies in India which are targets of acquisitions at present have turnovers below the thresholds introduced for target companies. The high level committee head by Mr. Arun Maira constituted by Planning Commission of India has recommended that “in case of pharmaceutical sector, the notification can be revisited to bring more combinations under the purview of merger review, as per the provisions the Competition Act 2012, in order to achieve the objective of adequate scrutiny of the drug industry’. However, the Central Government is empowered to enhance this threshold only ‘on the basis of the wholesale price index or fluctuations in the exchange rate of rupee of foreign currencies’. Therefore the remedy suggested is practically very difficult.
- The parameters within which the CCI can work would necessarily be circumscribed by the provisions of the Competition Act, which is structured around the determination of anti-competitive practices. The CCI may therefore, not be able to take on board public interest concerns related to public health.

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50 sub-section (3) of section 20 of the competition Act, 2002
CCI and Combinations Threshold

The acquisition of one or more enterprises by one or more persons or merger or amalgamation of enterprises shall be a combination of such enterprises and persons or enterprises, if—

(a) any acquisition where—

(i) the parties to the acquisition, being the acquirer and the enterprise, whose control, shares, voting rights or assets have been acquired or are being acquired jointly have,—

(A) either, in India, the assets of the value of more than rupees one thousand crores or turnover more than rupees three thousand crores; or

(B) in India or outside India, in aggregate, the assets of the value of more than five hundred million US dollars, including at least rupees five hundred crores in India, or turnover more than fifteen hundred million US dollars, including at least rupees fifteen hundred crores in India; or

(ii) the group, to which the enterprise whose control, shares, assets or voting rights have been acquired or are being acquired, would belong after the acquisition, jointly have or would jointly have,—

(A) either in India, the assets of the value of more than rupees four thousand crores or turnover more than rupees twelve thousand crores; or

(B) in India or outside India, in aggregate, the assets of the value of more than two billion US dollars, including at least rupees five hundred crores in India, or turnover more than six billion US dollars, including at least rupees fifteen hundred crores in India; or

(b) acquiring of control by a person over an enterprise when such person has already direct or indirect control over another enterprise engaged in production, distribution or trading of a similar or identical or substitutable goods or provision of a similar or identical or substitutable service, if—
(i) the enterprise over which control has been acquired along with the enterprise over which the acquirer already has direct or indirect control jointly have,—

(A) either in India, the assets of the value of more than rupees one thousand crores or turnover more than rupees three thousand crores; or

(B) [in India or outside India, in aggregate, the assets of the value of more than five hundred million US dollars, including at least rupees five hundred crores in India, or turnover more than fifteen hundred million US dollars, including at least rupees fifteen hundred crores in India; or]

(ii) the group, to which enterprise whose control has been acquired, or is being acquired, would belong after the acquisition, jointly have or would jointly have,—

(A) either in India, the assets of the value of more than rupees four thousand crores or turnover more than rupees twelve thousand crores; or

(B) [in India or outside India, in aggregate, the assets of the value of more than two billion US dollars, including at least rupees five hundred crores in India, or turnover more than six billion US dollars, including at least rupees fifteen hundred crores in India; or]

(c) any merger or amalgamation in which—

(i) the enterprise remaining after merger or the enterprise created as a result of the amalgamation, as the case may be, have,—

(A) either in India, the assets of the value of more than rupees one thousand crores or turnover more than rupees three thousand crores; or

(B) [in India or outside India, in aggregate, the assets of the value of more than five hundred million US dollars, including at least rupees five hundred crores in India, or turnover more}
than fifteen hundred million US dollars, including at least rupees fifteen hundred crores in India; or]
(ii) the group, to which the enterprise remaining after the merger or the enterprise created as a result of the amalgamation, would belong after the merger or the amalgamation, as the case may be, have or would have,—

(A) either in India, the assets of the value of more than rupees four-thousand crores or turnover more than rupees twelve thousand crores; or
(B)[in India or outside India, in aggregate, the assets of the value of more than two billion US dollars, including at least rupees five hundred crores in India, or turnover more than six billion US dollars, including at least rupees fifteen hundred crores in India;

Any merger or acquisition which exceeds the limits mentioned in Section 5 of the Competition Act 2002 requires an approval from CCI. However the majority of the pharmaceutical companies fall within these limits. Further only, those cases of combinations are required to be notified to CCI where the size of the acquired enterprise in India (the target company) based on turnover is beyond Rs. 750 crore and assets are beyond Rs 250 crore51. Threshold criteria have been increased by 50% by the Central government52. For this reason the high level committee headed by Mr. Arun Maira, suggested that the pharma Sector would need to be exempted from the operation of these notifications given the importance of this sector for Indian Healthcare requirements.

It may be noted that the most of the major acquisitions of Indian pharmaceutical companies made so far (Ranbaxy, wockhardt, Piramal, Vetrex Animal Health) would have required clearances from the CCI, had the provisions relating to combination in the Competition Act 2002

51 Notification, 4th march 2011, S.O.482(E)
52 Notification, 4th march 2011, S.O.480(E)
been made operative when those acquisitions were made. However today, very few companies fall within the amended threshold of the Competition Act 2002. This limits the jurisdiction of Competition Commission of India.

**Public Interest**

The real concern of the Central Government is the availability of cheap medicine to the people of India. The generic drugs have become a necessity for the poor class of India. The Competition commission of India only looks at sustaining the competition that was prevalent before the advent of foreign companies. It is not bothered with the question- what should be done to ensure adequate supply of generic. The composition and power of CCI is such that it can only ensure healthy competition amongst the pharmaceutical companies in India. The CCI, may therefore, not be able to take on board public interest concerns related to public health like:

- Ensuring adequate availability of essential drugs given the possibility of change in product-mix oriented towards developed markets that could be brought about by acquiring firms affecting the production capacity and supply of low priced generics. This would make health care and life saving medicines out of reach of large sections of the population around the world as India is the largest supplier of generic drugs especially anti-retroviral and anti cancer drugs.

- Ensuring that the FDI results in additional manufacturing capacity and is not merely a substitution which has been the case so far. Many of the acquisitions have been at astronomical valuations consisting amounts far in excess of those required to set-up even a green project.

- Enhancing investments in R&D for tropical diseases. The apprehension in case of such takeovers is that the thrust in R&D and could well shift to western and other country lifestyle diseases.

- Ensuring the availability of capacity to work a compulsory license in case of an epidemic or public health emergency. The ability of second tie companies to perform this role after top tier companies are taken over, is very limited.

The Foreign Investment Promotion Board (FIPB) is more equipped to deal with the question of public interest and the availability of generic drugs. The FIPB has its own drawbacks. It’s
opaque in its procedure. Its approach has connotations of the ‘license raj’ along with the impression of arbitrariness of government decisions. There is no certainty as to the time period required for FIPB to clear an acquisition. It may hold it indefinitely without specifying the reasons for doing so. And in the field of mergers and acquisitions, delaying the procedure of clearance of an acquisition is as good as denying it as it will result in the concerned companies incurring huge losses. The CCI is more transparent and accepted by the free economies all over, but it lacks the authority to look into the most of the mergers and acquisitions in the pharma industry for prescribed threshold and moreover it does not have the expertise to deal with the issue of public interest.

**The Present Policy on FDI in Pharma Industry**

As per the Central Government’s notification FDI upto 100 % would be permitted for brownfeild investment in the pharmaceutical sector, under the government approval route, while FDI upto 100% under automatic route, would continue to be permitted for greenfield investments under which investors have to only inform the Reserve Bank of India about the inflows and no specific nod from the government is required.

Under the new rules, for any merger or acquisition, the overseas investor will have to seek permission from FIPB. After six months, it will be the monopoly watchdog CCI, which will vet such details.
CONCLUSION

Pharmaceutical industry India plays a very crucial role in implementing the welfare state of the people. The economic growth of the industry along with the availability of generic goods and healthy competition is the need of the hour for India. After analyzing the pros and cons of the FDI in the Indian Pharmaceutical Industry, it is established that India needs adequate FDI and its spillovers for the growth of the industry.

The government has remained active in formulating policies to ensure overall growth of the industry. From 2001 onwards 100% FDI in pharmaceutical Industry has been allowed. This has benefitted the pharma sector. From 2006-10, as many as 6 top Indian Companies have been acquired by the MNCs. This has not resulted in price rise or limited supply of generic goods. India is a huge potential market for the MNCs with competent and cheap workforce. However the concerns relating to FDI in pharma sector remain. Though the statistics don’t show them, they may surface over a period of time. For this purpose some control of government over the FDI in pharma sector was needed. The Central Government has notified that in cases of brownfield investments in the pharmaceutical sector, FDI will be allowed through the FIPB approval path for a period of up to six months. In this period, the government will put in place the essential enabling mechanism for oversight by the competition commission of India. After six months, the oversight will be done by the Competition Commission of India (CCI) entirely in accordance with the competition laws of the country.

It seems that the current (FIPB) and the proposed (CCI) approval requirements may act as a speed breaker for potential foreign investors as they may have to show that their intention is not to collude or undertake predatory pricing or any such anti-competitive practice. If the government makes necessary amendments and CCI’s jurisdiction is enhanced to include all prominent pharma acquisitions by MNCs, it will ensure competition in the pharma industry in a transparent manner. With regards to the public interest concern, the Government can come-up with alternative public polices like public procurement of generic goods and fixing the price of essential drugs.

CCI, however remains a recently established institution. Its expertise is limited to the competition aspect of the industry. It remains untested, as of now. Government of India has taken a very optimistic decision to allow CCI to be the watchdog over all the mergers and
acquisitions in the pharma industry, but it must ensure that it brings about necessary amendments to the Competition Act 2002 and widen the scope of the commission.

RECOMMENDATIONS

The jurisdiction of the Competition Commission of India must be enhanced.
The word competition should be interpreted in the broadest possible manner. The CCI must take in the public interest aspect of the industry as well
A Standing Advisory Committee may be formed consisting of pharma experts to assist CCI.
The Government must look at the option of alternative public policies like public procurement of generic drugs. The domestic industry should be encouraged to produce cheap medicines. The R&D from the foreign companies must be encouraged.
Finally, all the companies in pharma industry must recognize that health and medicines are very essential even to the poorest of the country. Therefore, pharmaceutical companies, whether foreign or Indian, must rethink the broader purpose of their enterprise and their business models to fulfill this broader purpose.
The future leaders of this industry will be those, foreign or Indian, who voluntarily step forward to their responsibility to citizens by providing affordable and accessible medicines to all; who will cooperate with other agencies, in government, academia and the private sector, in corporation with whom they can discharge their responsibilities.