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# MASTERARBEIT

Titel der Masterarbeit

„Multinational pharmaceutical companies in India 1970 – 2005.
A case study of the pharmaceutical industry in India“

Verfasser

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angestrebter akademischer Grad

Master (MA)

Wien, 2013

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|---|---|
| Studienkennzahl lt. Studienblatt: | A 067 805 |
| Studienrichtung lt. Studienblatt: | Individuelles Masterstudium:<br>Global Studies – a European Perspective |
| Betreuerin / Betreuer: | Univ.-Prof. Alejandro Cunat, PhD |

the London School of Economics and Political Science

universität wien

# MASTERARBEIT / MASTER THESIS

Titel der Masterarbeit /Title of the master thesis

## Multinational pharmaceutical companies in India 1970 – 2005: A case study of the pharmaceutical industry in India


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angestrebter akademischer Grad / acadamic degree aspired

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**ACKNOWLEDGMENT**

This Master's Thesis would not have been possible without the support of many people, too many to thank individually. All my close friends that put up with me, proof read my thesis and let me bounced my ideas off them.

I would personally like to express my gratitude to my Master's Thesis supervisor Prof. Dr. Alejandro Cunat who was very helpful and offered invaluable assistance, support and guiding.

I extend my gratefulness to my mother and father for all the patience and support they have given me.

Lukas Guttek

# ABSTRACT

The pharmaceutical industry is nowadays one of the fastest growing industries within the Indian economy. Due to the industry's performance, expertise and state-of-the-art facilities, India has established itself as a major pharmaceutical hub. However, it took India for over four decades to emerge as the crucial player in the global context. The pharmaceutical industry went through fundamental structural changes that completely changed its face. During the 1950s and 1960s, thanks to quite liberal economic policy, Indian pharmaceutical industry got under the sway of foreign-owned pharmaceutical companies. As India's hopes for using expertise of multinational pharmaceutical companies (hereafter MNCs) to build domestic pharmaceutical capacities did not materialize, India tightened up policies which resulted in breaking dominance of MNCs in the pharmaceutical sector. Indian industrial policy was set in a way that favoured development of Indian drug companies at the expense of MNCs.

The thesis explores the development of the pharmaceutical industry in India from 1970 until 2005. It seeks to give insights into how drug companies responded to the changing economic environment and adapted their strategy to new conditions. Particular attention is given to the economic liberalization and thesis elaborates on why the effect of this process took some time to manifest in the pharmaceutical industry, especially MNCs.

The thesis argues that during the 1970s and 1980s the MNCs were keeping a low profile and were engaged mostly in non-essential business activities (production and the marketing of off-patented and basic drugs) and drug research and development. Besides, they were reluctant to invest and bring in the latest technology to India. Since the economic reforms and opening of India in the 1990s, there has been a surge of activity at MNCs. However, due to a slow pace of reforms and some persisting obstacles related to the protection of intellectual property rights, MNCs shunned away from unfolding fully their potential under these uncertain conditions.

# ABSTRACT

Die Pharmaindustrie ist heutzutage eine der am schnellsten wanchsenden Industriezweige in der Wirtschaft Indiens. Aufgrund der Industrieleistung, Kompetenz, und moderne Einrichtungenen etablierte sich Indien als weltweit wichtiges Pharmazentrum. Indien dauerte nur vier Dekaden, bis es schlüssiger Akteur in der globalen Pharmaindustrie wurde. Die pharmazeutische Industrie in Indien machte durch grundlegende strukturelle Veränderungen durch, die das Gesicht der Industrie schlechthin änderten. In den 1950er und 1960er Jahren, dank ziemlich liberaler Wirtschaftspolitik, indische Pharmaindustrie wurde von ausländischen Pharmaunternehmen dominiert. Indien hoffte darauf, die Wissen von multinationalen Unternehmen (fortan MNU) für den Aufbau von einheimischer pharmazeutischen Industrie zu benutzen. Als diese Erwartung nicht verwirklichte, zog Indien die Politik gegenüber ausländischen Pharmaunternehmen nach. Das hatte zur Folge, dass die Überlegenheit von MNU in der pharmazeutischen Industrie im Grunde gebrochen wurde. Indische Industriepolitik wurde damals so gestalltet, dass es die Entwicklung von indischen Pharmunternehmen auf Kosten von MNU bevorzugte.

Die Masterarbeit erforscht den Aspekt der Entwicklung der pharmazeutischen Industrie in Indien in dem Zeitraum von 1970 bis 2005. Es gewährt Einblick, inwiefern reagierten die Pharmaunternehmen auf die wandelnden wirtschaftlichen Gegebenheiten und passten an diesen neuen Umstände. Besondere Aufmerksamkeit ist der wirtschaftlichen Liberalisierung geschenkt. Die Masterarbeit geht mehr ins Detail, warum es so lange dauerte bis die Wirkungen der Liberalisierung von der 1990er Jahren sich in der Pharmaindustrie, besonders unter MNU, manifestierten.

Es ist argumentiert, dass in den 1970er und 1980er Jahren die MNU ein niedriges Profil hielten und sind meist in nicht-wesentlichen Geschäftstätigkeiten (Produktion und die Vermarktung von grundlegenden Medikamenten und die ohne Patent) und Forschung und Entwicklung tätig waren. Nur ungern investierten in Indien und brachten die neuesten Technologie nach hier. Aber mit den Wirtschaftsreformen und Öffnung von Indien in den 1990er Jahren bemerkt man einen Anstieg der Aktivitäten bei MNU. Doch aufgrund eines langsamen Tempos der Reformen und bestehender Hindernisse in Bezug auf den Schutz des geistigen Eigentums, hielten sich MNU davon fern, ihr Potential unter unsicheren Umständen völlig entfalteten.

# ABBREVIATIONS

| | |
|---|---|
| MNCs | multinational corporations |
| Lakh | one hundred thousand rupee |
| crore | ten million rupee |
| NDP | New Drug Policy |
| DPCO | Drug Price Control Order |
| GOI | Government of India |
| GSK | GlaxoSmithKline |
| NDDS | Novel drug delivery system |
| DRL | Dr. Reddy's Laboratories |
| GFA | gross fixed assets |
| R&D | research and development |

# Contents

# INTRODUCTION

The pharmaceutical industry has long been attracting a great deal of attention for its importance in keeping nations' health well. It is an exceptional success story of development, evolving from its meagre origins back in the 19th century into a technological and money-making heavyweight. Nowadays it ranks among the most technology-intensive sectors characterized additionally by a high degree of concentration, fierce competition, high entry barriers as well as strong profitability and a stringent regulation as against other sectors.

In India the set-up of the pharmaceutical industry is presently quite specific compared to what can be seen everywhere else in the world. Specific features of the pharmaceutical industry are a direct outcome of a distinctive economic path India took since the beginning of its independence. The pharmaceutical industry in India is markedly dominated by a small group of leading global drug makers along with large Indian pharmaceutical companies followed by a large group of minor drug manufacturers. Following the tumultuous years of structural transformation spanning the 1970s and 1980s, the Indian pharmaceutical industry emerged as a leading player in the field of generic drugs in the world that had to be counted with. It began to rival entrenched pharmaceutical companies from developed countries and challenge their unshakeable position in India and everywhere else. Vigorously acquiring expertise in drug research and development along with overhauling production facilities to Western standards, Indian drug companies have gradually been catching up with companies from advanced countries. Successful restructuring of the Indian pharmaceutical industry ensured India earned the label of "the pharmacy of the world", a global manufacturing hub of generic drugs for other countries around the world that cannot afford or do not have necessary know-how, expertise and infrastructure.

On the way to this prominent position, India passed through a different phases in its economic development. Before the Second World War, India was recognised as a country with one of the most open economies in the world. In the following period, after declaring independence, India reversed the then orientation and adopted an inward looking economic policy with the aim to building local industrial capabilities and expertise. The policy reached its peak during the 1970s and 1980s when India, in addition, implemented measures that considerably restricted operations of foreign companies in India. With the worsening economic performance, increasing deficit of the balance of trade, and losing its competitiveness edge, India began slowly making a U-turn. At the onset of the 1990s Indian launched major economic reforms that ushered in a new era of economic openness and full-fledged integration into the global economy. The Indian pharmaceutical industry developed

against this backdrop and followed to a great extent the path of the overall economic development in India with all its ups and downs.

It is necessary to point out to the fact that foreign-owned companies, on one hand, and Indian drug companies, on the other, followed a different path over the years. Due to legislations having different impact on both groups, MNCs were, ultimately, affected by actions of the Government of India (hereafter GOI) to a greater extent than their Indian counterparts.

At the beginning of the 1950s the foreign pharmaceutical companies were hailed in India for its expertise and know-how that was desperately needed at that time. They were believed to contribute to the development of India's innovative capabilities in the domestic pharmaceutical sector. In the ensuing years it increasingly became evident that this assumption fell short of. At the end of the 1960s the Indian pharmaceutical sector looked as underdeveloped as it was at the beginning of the 1950s. As a result of that, India adopted a tougher approach and modified legislation in a way that made operations of MNCs in India more difficult. The 1970s was a turning point for MNCs in the sense that their expansion in India was stalled for two decades. India's determination to curb the power of MNCs was manifested through a number of restrictions on foreign investments, profit transfer, drug pricing and most importantly through changes in the intellectual property regime. In an effort of getting most benefits of MNCs to build up local pharmaceutical capacities and expertise, GOI took far-reaching measures that entirely changed the face of the industry in India. Over the next two decades, it managed to break the dominance of MNCs in India while creating an environment conducive to the expansion and growth of domestic pharmaceutical companies.

Even though the pharmaceutical industry belongs among high technology sectors of the economy, the adverse economic policy at that time, especially towards MNCs, resulted in the pharmaceutical industry taking the less technology intensive path of development. The pharmaceutical industry ceased to be dominated by MNCs which were step by step replaced at the helm by drug companies of Indian origin. This trend proved to be irreversible even after the restrictive policy towards MNCs was attenuated in the 1990s. It took only two decades for domestic drug makers to take over the rein in the pharmaceutical industry from MNCs and to establish themselves as strong challengers to MNCs than they were back in the 1970s.

The Indian pharmaceutical industry is currently one of the most vigorously growing industries in India, growing at about 15 to 20% annually. Besides, it has become the biggest producer of off-patent, generic drugs in the world. And what is particularly interesting about India is the fact that it is

counted among few countries whose pharmaceutical industry is not under the control of entrenched global pharmaceutical players.

The analysis attempts to provide answers, first, to what changes entailed Indian economic policies over the past decades for the working of the pharmaceutical industry, how pharmaceutical companies, especially MNCs, responded to the changing institutional framework and what kind of strategy these companies adopted.

## *Literature review*

Despite the lack of the authoritative research on strategies of pharmaceutical companies in India, there are a large number of scientific papers dealing with diverse aspects of operations of the pharmaceutical MNCs in India, particular drug policies and general economic environment. Putting it together, they provide a colourful picture of the Indian pharmaceutical industry and its development.

The Master's thesis examines how specific aspects of government policy impacted upon the operations of MNCs in India. For example, the patent law and intellectual property protection have long been one of the most crucial aspects which concern most the pharmaceutical MNCs. This issue was elaborated at length by several authors - Chaudhuri (2005), Bhatacharrya (2004), Fink (2001), Rao (2007) to name but a few. These authors share the view that weak patent protection from the 1970s until 2005 induced especially MNCs to stay away from importation of on-patent drugs. Besides, weak IP environment was a factor inhibiting transfer of the technology to India because of the danger of proprietary knowledge leakage. The same goes for the drug price policies which were viewed as a major inhibiting force in unfolding innovative potential of the pharmaceutical MNCs in India. Nevertheless there is not always a unanimous view for judgment. Narayana (1984), for instance, maintained that drug price controls were the major negative factor affecting not only R&D, but also investment, productivity, and profitability of all pharmaceutical companies, chiefly MNCs. However, there were also opposing views represented, for example, by Singh (1985) who argued that the ramifications of price control were not as severe and grievances of the MNCs are, therefore, unfounded.

As for the strategy of the pharmaceutical MNCs during the post-reform period, there are two main arguments. As Chaudhuri (2004) argued, MNCs backed away from investment activities in favour of importing pharmaceutical products from abroad benefiting from the liberalized economic conditions

coming slowly closer to Western standards. On the other hand, Smith (2000) claimed the pharmaceutical MNCs attempt to renew their market monopoly and to strengthen their position by investing heavily in manufacturing in India.

Much has been published about the Indian pharmaceutical industry focusing on the period since the declaration of Indian independence until the end of the 1970s and after the economic reforms in the 1990s. In contrast, there has been very little published about the pharmaceutical industry for the 1980s and the transition era shortly before and after reform process.

Vital information on MNCs were drawn from works that deal with specific issues related to the pharmaceutical industry as a whole (Mittal 1993, Karandikar 1994) or focus on foreign multinational companies operating in India in general (Kumar 1990, Singh 2007). In addition, MNCs are discussed in the context of foreign direct investment to India in the work by Chopra 2003, Gakhar 2006, Ray 2005. This is complemented by information and insights sourced from special periodicals like The Eastern Pharmacist, India Pharmaceuticals and Healthcare Report and Economic and Political Weekly.

## *Problem statement*

The objective of this paper is to provide analysis of one of the key and most vigorously developing sectors in India nowadays – the pharmaceuticals. In so doing, the paper focuses on deals with the corporate strategy of multinational pharmaceutical companies (hereafter MNCs) from the 1970s until 2005 and draws the line between foreign-owned and Indian pharmaceutical companies.

In spite of some previous research performed to date on the pharmaceutical industry of India, the issue of business strategies of pharmaceutical companies in India has not yet been fully elaborated. One of the critical aspects of the presented analysis is to understand the way pharmaceutical companies responded to changing economic conditions and the institutional framework in India in the period from the pre-1970s to 2005.

It attempts to analyze three distinct periods and show effects of institutions on the pharmaceutical companies. It is divided into following periods. First period covers the time until the end of the 1960s, which was generally seen as a period of liberal economic order. Second period deals with the 1970s and 1980s, regarded as the period of adverse policy towards foreign-owned companies and foreign investment themselves. This economic policy was gradually reversed from the beginning of

the 1990s, which marks the beginning of the third period and continues up to 2005 – the year that India began to grant patent on product and not only on a process.

For all three distinct periods, the paper attempts to shed light on how state economic policies influenced working of MNCs in India. It seeks to illustrate the effect of India economic policies on areas such as sales, investment and R&D and others.

Generally speaking, the economic environment framed by institutions affects to a great extent the overall behaviour of firms. The way companies behave can have both positive and negative consequences for the economy itself. Since the pharmaceutical industry as a knowledge-intensive industry is crucial for keeping the nation's health, it had often been a target of state's intervention attempting to guide it to the benefit of a state. Nowhere else it can better be illustrated than on the case of India. The government of India greatly interfered in the pharmaceutical industry with an ultimate goal of promoting development of local companies and building up domestic capacities. By tilting a regulatory table against MNCs in the 1970 and 1980s, India effectively curbed the power of leading foreign drug makers and made it easy for Indian companies to develop and thrive on the back of MNC's proprietary knowledge. Actions of GOI led to decreasing profitability in the pharmaceutical industry which entailed low R&D content in the whole drug industry; however larger losses were incurred by MNCs than local companies. India thus successfully managed to guide MNCs in a way that it best suited its objectives. Yet that came with costs. MNCs that were incomparably more subject to regulations than local drug companies opted to keep rather a low profile and limited activities in India, only within the scope of what was required by then effective laws.

And yet foreign companies managed to adapt themselves to the tough conditions of the 1970s and the 1980s and changed their business strategy accordingly rather than pulling themselves out of the Indian market altogether. The MNCs strove every which way to exploit opportunities left to them to improve their business results by branching out into non-related areas of products, where they could at least partly capitalise on their expertise and capabilities. Other possibility was to shift the product portfolio more towards non-regulated lines of products.

When the time dawned for India in the 1990s to make wide-ranging changes in its economy and pharmaceutical policies, the core of its Indian drug companies had already been firmly established. The breathing space provided for Indian drug-makers in the 1970s and 1980s enabled them to emerge as a power that need to be counted with. In the 1990s Indian drug companies appeared to be well equipped and strong enough to stand up to global competition.

The new period heralded by the economic reforms in 1991, ended the adverse policies towards foreign investment and put MNCs on more or less equal footing with local drug makers. They were enabled to grow robustly in the following years. In what manner MNCs responded to and take advantage of new liberal economic conditions varied case by case and the answer to that is part of this analysis. It appears that MNCs have been quite wary as the IP environment was still in a state of flux and the regime of product patent was only slowly coming into existence. MNCs began reaping benefits of new economic conditions quite late and compared to Indian companies grew at a slower pace in sales and fixed assets; however from much more developed stages than their Indian rivals.

The paper also challenges earlier arguments related to activities of pharmaceutical companies in the post 1990s period. It rebuts that MNCs made use of relaxed economic conditions of the 1990s, partly de-invested their production facilities and shifted more towards drugs importation to India as employed in the period before the 1970s. Furthermore the paper looks into the profitability of the pharmaceutical companies and attempts to provide an answer as to why increased margins did not translate into higher R&D spending. Since the issue of intellectual property is quite crucial for the pharmaceutical industry, the paper explores this aspect through the theory of industrial organizations and intellectual property rights.

The paper does not have an ambition to be a comprehensive analysis of the development of the pharmaceutical industry in India. It rather attempts to look into certain aspects, to highlight important milestones that shaped up the sector during the period under consideration, the effect of regulation and economic policies on pharmaceutical companies both foreign and Indian ones and how they responded to these changing economic conditions.

## *Methodology*

With the aim to analyse a particular sector in India, I focused on the pharmaceutical sector since it is one of the key industries in India nowadays. I seek to provide a picture of the Indian pharmaceutical industry, by analysing general and drug industry-specific policies with their impact on the pharmaceutical sector. Besides, I drew on financial figures in order to illustrate the impact of regulations at the company level.

Yet, during the research phase, problems arose as to primary data since there is lack of necessary time series data for the pre-1991 period which made the analysis a difficult task. Specifically, I

encountered a problem of obtaining data covering the period of the 1970s and 1980s. Due to the fact that there was no mandatory provision for companies in India to make the corporate financial results public at that time, companies were not obliged to publish their annual results and to make it available to the public. Therefore it was an arduous task to gather any substantive time-series data for that period. By account of scholars researching the pharmaceutical industry of that time, even they admitted that they themselves came across lack of appropriate data with which they only coped with difficulties in their research. As a result, the data for that period for my analysis are compiled from a variety of secondary resources published by authors, like Narayana (1984), Singh (1985) or Bhagat (1982). Though limited in scope, these data proved to be invaluable in providing insights in the Indian pharmaceutical industry of that time. Unfortunately, disparate data sets for the pre- and post-1991, however, make the overall comparison with the post 1991 period practically impossible.

As far as the period from 1991 onwards is concerned, the situation with data was much better. I drew on data from Prowess database administered by the Centre for Monitoring Indian Economy Ltd., which is a database of the financial performance of over 27 000 companies operating in India. For the purpose of this analysis, I put together a sample of 15 companies comprising ten largest (according to sales record in 2001) foreign pharmaceutical companies[1] (hereafter MNCs) complemented by five biggest companies of Indian origins[2]. I attempted to analyse data for sales, R&D, gross fixed asset, profitability and import/export for each of them to identify common trends in the pharmaceutical industry. The chief objective was to get a better comprehension of how businesses responded to the changing policy environment and adapted their strategy accordingly. Thanks to data, we are able to get a picture of trends on part of MNCs and Indian drug makers.

In addition, the analysis is backed up by an extensive list of secondary literature focusing on policy- and business-side of the pharmaceutical industry.

### *Structure*

The Master's thesis is divided in several chapters. The "Conceptual framework" chapter elaborates on the theory of the Industrial organization to explain the development of the pharmaceutical industry. It deals with aspects such as the role of intellectual property, monopoly and

[1] Abbott India, AstraZeneca Pharma India, Aventis Pharma, Fulford (India), GlaxoSmithKline Pharmaceuticals, Merck, Novartis India, Organon (India), Pfizer, Wyeth

[2] Aurobindo Pharma, Cipla, Dr. Reddy's Laboratories, Piramal Healthcare, Ranbaxy Laboratories

the level of competition that all have influence on the structure and working of the pharmaceutical industry. The next chapter provides a brief history of the pharmaceutical industry in India in the period up to the 1960s and pays attention to the origins of MNCs in India. In the following chapters, the core of analysis is presented. The analysis is divided according to specific periods – First, the 1970s and 1980s (the chapter "Difficult years"), and then from the 1990s until 2005 ("Years of expansion"). Both chapters follow the same line. First, the general environment and policy is outlined, followed by specific policies closely related to or directly affecting the pharmaceutical industry. Thereafter, in the main part, the paper looks into the effect of these specific policies and regulations having on the pharmaceutical industry, in general, and MNCs, in particular. And, furthermore, it sheds a light on how pharmaceutical companies responded to the changing institutional framework. At the end, the main findings of the analysis are summed up in the concluding remarks. A list of tables and secondary sources complement the analysis.

# CONCEPTUAL FRAMEWORK

The rise of the Indian pharmaceutical industry was conditioned by few factors, notably by modifications to the intellectual property regime in the 1970s that entailed far-reaching ramifications for the whole pharmaceutical sector. By shortening the period of patent protection along with granting a patent on process in parallel to a product, GOI completely changed the rules of game and resultantly the future face of the sector. By facilitating the access to and the exploitation of the proprietary knowledge embedded in proprietary drugs through modified patent laws, GOI provided an important instrument for Indian pharmaceutical drug companies to expand.

The issue of intellectual property rights (hereafter IPRs) is the golden thread of the pharmaceutical industry since the existence of the sector. The industry is heavily dependent on the IPR protection and proper enforcement regime due to its knowledge-intensive nature. There is barely any other industry besides the pharmaceutical which would link its competitive advantage more closely to IPRs. Proper securing and enforcement of IPRs thus became the lynchpin for pharmaceutical companies and central to their reasoning as far as strategy and R&D involvement is concerned.

The extent and scope of granted protection, however, is crucial in this debate and as it will be said later, it might act both as a powerful incentive and barrier to the development of the pharmaceutical

industry. India is a case in point in demonstrating both positive and negative effects IPRs have had on its economy in the long run.

IP right, in a nutshell, is a non-market institution that is to prevent competitors from making full use of invention/innovation of originators by providing an originator with exclusive rights to the innovative process and product, respectively, it developed. There exists a variety of the IPR regime governance differing from each other in a way benefits accrue to participants in this process. The IP protection takes on various forms ranging from patents (in the case of knowledge embedded in novel ideas), trade secrets, copyrights to trademarks and others. Specifically patents and copyrights are regarded as an important strategic, knowledge-based asset for owners since they grant their holders inviolable ownership, a license, to work the innovation. As Andersen and Konzelmann put it, this, however, resulted in IP being a constantly privatized knowledge-based asset (Andersen, Konzelmann 2008: 12).

Given the fact that the knowledge possession is an effective instrument in pre-empting competing firms from entering a particular market segment and in weakening an existing monopolistic position of current market leader, it elicited a criticism of those who seek to disrupt the mighty role IP plays in the world. In their views, companies launch multiple products and apply multiple times for patents of substances with minor improvements only to “reserve” a certain market segment for themselves. That furthermore leads to solidifying the monopolistic structure of the respective market segment. That undoubtedly raises market barriers high and becomes an obstacle for the economic development of a country. Yet the other part present in this debate represented by a number of stakeholders such as specific industries, governments and international agencies vehemently counters that privatization of the knowledge confers a great deal of advantages associated with the business performance (through knowledge spillovers) on companies and are equally beneficial to the economy as well (Andersen, Konzelmann 2008: 14).

The reason why IPRs are nowadays so heftily defended is that they are recognized to provide economic incentives for companies to engage in innovative and knowledge creative activities, which subsequently stimulate market development, increases competition and unfold the economic potential of a particular country. Nevertheless, it is also argued that as much beneficial as they can be, IPRs can also give rise to problems of their own. Most issues arise in regard to their structure, and lack and mismanagement of their protection. It is widely claimed that IPRs are one of major obstacles for an economy to run smoothly. Andersen and Konzelmann further maintain that an excessively strong IPR regime can be an effective hindrance to the development of regions, countries, sectors and firms. Instead of bringing convergence and narrowing down an income and technology gap, an

overly stringent IPR structure curbs innovation-based competition, weakens spillover effects in the economy and makes sustainable development of firms more difficult (Andersen, Konzelmann 2008: 13, 17).

The IPR regime proves to have a fundamental effect on the intensity of R&D performed at a firm level and within a country. Research and development help companies differentiate themselves from one another and if successful it gives them competitive edge vis-à-vis their counterparts and help consolidate their market position. As such, R&D is widely referred to as a strategic weapon of a firm in its quest for revenues, a competitive advantage and a larger market share (Dasgupta 1988: 66).

By pursuing R&D a company produces and embeds information in a product and process. Through working this information, a firm can bring about a technological change, disrupt the status quo in a market and open up new market opportunities for itself (Hay, Morris 1991: 466-467). Nevertheless, that only takes place if IPRs are secured and properly enforced. Hence, the scope of patent protection plays as an important role as does the overall IPR set-up in this context. Taking all factors into account, IPRs act as a major determinant for firms whether to embark and expand on the R&D front or to keep rather a low profile in that field. As Hay and Morris point out, the propensity to seeking out a patent protection varies among sectors and even companies alone. As for the pharmaceutical industry, due to a high risk involved in the knowledge-generating process, drug companies are, in general, heavily disposed to securing patents in order to safeguard results of their R&D activities (Hay, Morris 1991: 469).

Differences in viewing IP are especially evident between developed and developing countries. As for the former, IP rights and their due enforcement feature high on the list of important issues and these countries constantly push for ever more rigorous protection standards in this context. By contrast, developing countries tend to oppose stringent IP rules, viewing IP rights largely as a mean for transferring rent by companies from high-income countries. According to Markusen, an appropriate IP rights regime that is moulded on standards common in developed countries enriches companies from developed countries operating in developing countries; however, it also confers benefits to developing countries. Strong legal protection of IP can result in a disproportionate high level of foreign investment flowing in a developing country that has such a protective regime in place (Markusen 2001: 189, 203). Therefore, an authoritative judgment of the positive or negative effects of IP regime for a country is not easy to provide in this place.

A similar view is also held by Vishwasrao. According to him, the world has polarized around the issue of IP rights into a camp of developed Northern countries, on one hand, and developing Southern

countries, on the other. In his opinion, Northern countries, which undertake the preponderance of R&D activities and call for a high level of protection standards, clash with the Southern countries that usually do not have strong IP rights regime in place and seek to gain access to the pool of existing innovations. In countries with minimal R&D activities, strong free riding incentives exist and patent protection is not necessarily welfare enhancing in this respect (Vishwasrao 1994: 381-382). Here the danger of imitation is all the more imminent in such an environment.

In essence, the level of innovative activities performed by a company corresponds to a great extent to the degree of IP protection granted in the given country. Yet, the weak patent regime with its loose interpretation of patent laws works against this assumption and is not instrumental in strengthening the R&D environment in the country. The infringement of patent rights due to weak enforcement mechanism inflicts a significant cost to innovating firms and, consequently, helps alter companies' strategy with respect to what kind of R&D and technology are employed in a country. Specifically, patent infringement provides an internationalization stimulus for a foreign company operating in a given country to rather invest in other country. By establishing a new wholly-owned subsidiary in another country, the company prefers to produce and export patented products rather than licensing them locally. This imposes costs on Southern countries as innovative products will not be manufactured by local companies but by foreign companies and not for the local market. As a result, Southern countries attempt to counteract by imposing various restrictions on foreign direct investment (hereafter FDI) and foreign-owned companies, ranging from compulsory licensing to restrictions on the repatriations of profits in order to reach their proprietary knowledge. Sometimes such measures work and prompt foreign companies to license their patented products. However, that is not always the case as Vishwasrao suggests (Vishwasrao 1994: 383).

Following licensing, when imitated product is brought on the market, the Southern company produces a perfect substitute of the licensed product and avoids royalty payments to the Northern firm. What's more, it enters into direct competition with the originator firm. The result is that Southern firm, which infringes the patent, is allowed to compete at lower costs against Northern firms in both local and global markets. This situation is commonly referred to as Cournot competition where firms do not compete on quantity but on price (Vishwasrao 1994: 386-387). The danger of product imitation is to a large degree determined by technological capacities within the country that enable to exploit and utilize knowledge and to transform it into a novel process or product.

Yet foreign-owned companies might avoid the scenario of licensing a product by establishing a wholly-owned subsidiary in the Southern country. In that case the payment of royalties and lump-sum is abandoned as the threat of imitation is not present anymore. Nevertheless, the seamy side of

having an own subsidiary is that such an affiliate is not able to match the local companies in some regards. It does not have such a developed market reach, enjoys much lower level of brand awareness and lacks the necessary knowledge of the local market. On the contrary, when the foreign company is well established in the particular market, the fixed costs associated with above mentioned categories are close to zero (Vishwasrao 1994: 395).

There has long been a debate whether or not concentration and monopoly hamper innovation and whether competition can exacerbate or enhance the dynamics of innovative activities. According to Hay and Morris, one point of view is that a monopolistic firm will always be alert to deploy more resources for innovation than its rivals, since the returns to monopoly is much higher than the returns to the duopoly. Consequently, the monopolist is always set to pre-empt the inroads of rivals that would eat away its market share and revenues (Hay, Morris 1991: 481). By others, the monopolist has less incentive to innovate than entrants because the monopolist already earns above-average profits. This begs a question which firm has greater incentive to win the next patent race. The answer hinges, according to Hay and Morris, on two factors – first, the reduction costs generated by innovation and, second, the nature of competition in the product market.

If there is Cournot competition, if the initial cost disparity is not too great, and if the innovation is not going to generate a major cost reduction, then the incentive dictates that a high-cost firm will innovate; the industry remains a duopoly with the leadership changing at each innovation turn. Yet if the innovation is sufficiently 'drastic', and the market is more competitive than the Cournot one, winning the patent race can bring in the prize of driving the rival out of the top spot (Hay, Morris 1991: 482).

According to Barzel's allegation, competition among innovators might help drive innovation ahead at a rapid pace, whereas monopolist innovators who do not face potential rivals can considerably slow down the intensity of R&D activities. Based on Tirole's observation, two factors play a fundamental role in the innovation process – an efficiency effect and a replacement effect. Since monopoly profits will always be higher than oligopoly profits in any given market, a monopoly firm has always inclination to pursue R&D much vigorously in order to safeguard its dominant position. Entrants, on the contrary, aim to innovate in order to transform monopolistic market into a duopoly. This is called an efficiency effect. In the case of a replacement effect, a monopolist has less to gain from innovation since it already earns monopoly profits. Consequently, a monopolist may not have as much to gain from innovating as compared to a potential entrant (Tirole 1988). There exist two scenarios in which one effect is more prevalent than the other. In the case of drastic innovation, the replacement effect dominates since the entrant becomes a monopolist. In the context of non-drastic

innovation, the efficiency effect is predominant, and, hence, the monopolistic market structure tends to persist (Menell 1999: 138).

The other question that occupies mind of experts and which is hard to answer unambiguously is whether concentration can affect the degree of R&D. Firms will produce more than one product, and will position them in the product space deliberately to avoid leaving gaps in the market for a new entrant. If the product innovation is successful, the firm may use the location of new products as an entry-deterring strategy. Still there is a little positive correlation between R&D and concentration. It is difficult to maintain that concentration is undoubtedly an independent and significant determinant of innovative activity and performance at the firm level (Carlton, Gertner 2002:14).

Rosenberg in his seminal work maintains that a firm with a large market share will have less incentive to innovate than a small one due to that fact that it has already carved out a large market share up to that point that no additional investment is necessary (Rosenberg 1976: 105-112). Hay and Morris look at the matter from a different angel. They identify companies pursuing the “offensive strategy” and those with the “defensive” one. Whereas the former employs offensive strategy in an attempt to become the market leader, the objective of the latter is to take in and capitalize on innovative processes and products developed by competitors. Companies in the latter case are commonly labelled as followers (Hay, Morris 1991: 488).

According to the industrial organization theory, in the process of innovation the positive results are never assured to be achieved beforehand. Virtually it is a race over time between monopolists and rivals to be the first to reap the benefits of R&D if successful. R&D activities at the firm level are furthermore influenced by information asymmetries arising between incumbent patent-holders, on one hand, and rivals, on the other, who aim to win the next patent race (Hay, Morris 1991: 478). Yet, the incentive to innovate from the point of view of companies is considerably reduced by the existence of spillover effects, such as licensing and imitation. As Dasgupta confirm, if spillovers are enough strong, firms will prefer to stay followers, thereby shunning away from major innovation. The result is a “waiting game”, where each firm hopes that others will innovate (Dasgupta 1988: 75). However, under the conditions of a full-fledged patent protection on both products and processes, a technological leader has a strategic advantage vis-à-vis counterparts. Such a company is in a position to discourage others from undertaking their innovative activities, thus ensuring that its superior position is not eroded by rivals (Hay, Morris 1991: 480). Generally speaking, most front-runner patent holders thus have much greater incentive to innovate than followers. The rationale behind it is that if a rival gains the patent, the market would become a duopoly and profits for a market leader would decrease. Yet, if the current patent holder maintains its advantage through patent, the

markets remain monopolistic in the future. Considering the amount of profit that would flow to the incumbent patent-holder, it is, at any rate, advantageous if the market is preserved as monopolistic.

Government can greatly improve the overall rate of innovation and R&D at the firm level in a given economy. Government is able to boost the rate of innovation in the economy by deploying an instrument called the duration of patent protection. In theory there are many views of the optimal length of the patent protection. According to the Nordhaus model, it is proved that the optimal duration of patents is longer in an environment where enforcement is costly or incomplete and where compulsory licensing at low rates is possible. On the other hand, optimal duration of patents is shorter where rivalry among firms raises the cost of innovation and where prospective competitors may waste resources by inventing around patents (Menell 1999: 138).

# CASE STUDY: MNCS AND INDIAN PHARMACEUTICAL INDUSTRY

## THE ORIGINS OF THE PHARMACEUTICAL INDUSTRY IN INDIA

The modern base of the Indian pharmaceutical industry compared to other sectors is relatively a new phenomenon. Origins of the drug industry in India go back to the beginning of the 20$^{th}$ century when first of many drug companies, Bengal Chemicals and Pharmaceutical Works, was set up in Calcutta followed Alembic Chemical Works in Baroda in 1901 (Rao 2007: 11). After the First World War foreign multinational pharmaceutical companies (hereafter MNCs) set foot in India, with Glaxo being the first among them establishing its branch in 1924 (Lall 1980: 162). A true expansion of the pharmaceutical sector began after India declared its independence and the genesis of Indian subsidiaries of some of major MNCs dates back to the 1950s.

India back then had very specific industrial structure which was the result of its colonial past. There was not nearly any sector that would have not been dominated by foreign companies. The philosophy of economic self-reliance and self-sufficiency was very popular in reasoning of GOI. India sought to follow this strategy; however, due to a high level of the economic backwardness, it could not entirely afford it. The unpleasant fact was that Indian economy was to a great degree backward and underdeveloped in terms of capital goods. India was well aware of its inability to industrialize the

country from its own resources. It did not possess any necessary capacity, capital or expertise to develop its economy.

To climb up the development ladder, India needed assistance from outside in the form of FDI. In the 1950 and 1960 FDI regime in India was very liberal and GOI welcomed foreign companies bringing expertise, technology and other key resources. Despite some opinions, emerging from time to time, demanding regulation of the foreign capital flow more in the 'national interest', no effective regulation of foreign companies was put in place then. The Industrial Policy Resolution of April 1948, accepted as the major guiding principle document for the economic development of India for the years to come, was free of any mention of this issue. Foreign investment, as stipulated in the document, were regarded as an essential addendum, supplemented Indian capital and extended the available resource base for industrialization of India (Kumar 1990: 8).

As a consequence, foreign investors were assured of no constraints on the remittances of dividends, profits and other payments abroad. Subsidiaries of MNCs were treated on par with Indian counterparts. Furthermore, in case of the prospective nationalization of their assets, MNCs were guaranteed to get a fair price for a confiscated plant (Kumar 1990: 9). Though preferable for Indians to secure the majority stake, and thus ownership, in companies, this could not have been possible. This is particularly true for the pharmaceutical sector, where only major foreign players had necessary technology and expertise to help overcome the technological backwardness of India. Here India was entirely thrown back on MNCs for their know-how, best practices and research. The newly created state concentrated its effort on industrialization rather than self-reliance, which should be reached as of the next stage. However, in contrast to usual practices in other sectors, the GOI did not hamper operations of MNCs in the pharmaceutical industry. The rationale behind it lies in that India did not have any suitable substitutes for MNCs technology and expertise on hand. At that time keeping the national health stood higher on the agenda than achieving self-reliance (Smith 2000: 13).

Over the time it proved that more India sought to accommodate MNCs through establishing a favourable business environment for their operations, the stronger the flow of FDI was to India. In April 1956 GOI released a new industrial policy in which India further liberalized the environment for FDI. GOI provided a great variety of incentives ranging from tax concessions on salaries and wealth tax, reduction of corporate tax on income and royalties to MNCs. Looming foreign exchange bottleneck prompted GOI to change direction. On that account it opened some of profitable industries that were earlier reserved for local companies, such as drugs, aluminium and chemicals, to the foreign capital (Kumar 1990: 10). As a result, after 1957 there is seen a large surge in foreign investment in India. It was precisely at that time that most major pharmaceutical companies

established their subsidiaries in India. However, this approach proved to have a double-edge effect for India (Smith 2000: 13).

Foreign pharmaceutical companies were welcomed with open arms as it was expected that they will bring expertise and resources necessary for developing the sector from scratch (Rao 2000: 12). For MNC, India was attractive due to the market size, relatively high demand for drugs which implies probability of high profits, no strong control over industry-specific aspects, lack of domestic competition and, last but not least, the advantage of protected market behind tariffs and import barriers that enabled MNCs to soon assume monopolistic position (Singh 1985: 102-103).

MNCs, however, followed a different strategy in India as compared with that in their countries of origin. They clearly appreciated the potential of India, despite the fact that Indian was at the time wrestling with problems as an unequal and income distribution, high level of poverty, non-existent social security, inadequate infrastructure and others. In this context, MNCs soon build up dominant positions in India and held sway over the pharmaceutical sector. Except few local pharmaceutical companies, the domestic pharmaceutical sector was tiny in size. Consequently, there was no power to stand MNCs in the way to rise to the rank of monopolistic players. The development path of the pharmaceutical industry was determined by the overall framework of the industrialization of India and later was significantly affected by interference of GOI to guide the sector with mixed success. Yet the 1950s were mostly characterized by a friendly stance of GOI towards MNCs. From the onset MNCs followed a strategy of importing prepared drugs to India which was later modified into importing active drug ingredients (so-called bulk drugs) to India and formulating them into final products (so-called formulations). This formulations-focused approach has one undisputed advantage for MNCs – it did not require for them to employ any state-of-the-art technology. This had a consequential ramification for India. Importing of expensive bulk drugs caused a great burden for India and its balance of trade. MNCs took advantage of the circumstances. Importing drugs allow them that they need not have kept large manufacturing plants and work force in India and need not have involved in import of technology and pursuing R&D in India. Although later companies altered their strategy and set up a manufacturing facility just on a small scale in India, they nevertheless did not fully engage in R&D and kept it rather in developed countries. They could simply have maintained their oligopolistic positions in India without using their most valuable asset there – the branded drugs. For MNCs, India market, though flawed and underdeveloped along with weak purchasing power, posed a great lure with a bright prospect of growth in the future (Joseph 2009: 16).

Strategy of MNCs in the 1950s and the 1960s reflected the overall liberal environment in which they operated. Since setting their foot in India, they hardly engaged in production of bulk drugs or in

research which were in fact two sides of the same coin. While bulk drug production can be sustained over a long period only through sustained involvement in research and development (R&D) activities, formulations production can be carried out relatively low level technological sophistication (Dhar, Gopakumar 2007: 53). Instead of being involved in technologically intensive bulk production, they rather imported these and active chemical ingredients, which they fabricated on site into final products as tablets, ointments, syrups, injections etc. Though generally the pharmaceutical industry is regarded as a high technology sector, this was not true for India. The formulation line of business which did not require high technology was far more profitable contrary to the manufacturing from basic stages which was considerably technology intensive. Despite MNCs engagement, the Indian pharmaceutical industry of the 1960s remained as much technologically underdeveloped as it was at the beginning of the Independence. In those cases where MNCs undertook production of drugs from basic stages, it occurred at very limited scale and never made a core activity of the company (Sahu 1998: 55-56; Chaudhuri 2005: 277-279).

Moreover, the patent system of the time was also instrumental for MNCs to safeguard their monopolistic position. MNCs exploited the possibilities offered by the patent system to block others to take up production of drugs patented by them, thus ensuring them a huge market power. Between 80 to 90 per cent of all patents filed in India were in hands of MNCs. What was more striking was that 90 per cent of those patents were not at work in India. This means that patented drugs were registered, yet MNCs did not produce them, only blocking the market segment against other competitors (Joseph 2009: 16).

Over time the ominous degree of dependence of India on MNCs became increasingly apparent. Despite all efforts to develop the pharmaceutical industry with the assistance of MNCs, the pharmaceutical sector looked much the same at the end of the 1960s as in the 1950s. Realizing that the expectations put into MNCs did not materialize India took u-turn in its policy towards foreign companies and began increasingly intervening in the economy. The era of liberal policy of the 1950a and the 1960s toward foreign investment was over and from the 1970s it was replaced by more targeted and regulatory policy.

# DIFFICULT YEARS

# THE PHARMACEUTICAL INDUSTRY IN THE 1970s AND THE 1980s

## *General regulatory environment*

At the onset of the 1970s, India took steps to reassess its policy towards MNCs. Following more than two decades of relatively unhindered boom of MNCs in India, GOI initiated measures to tighten a grip on MNCs. Reasons for the shift was the inadequate progress in the development of local companies (that applied, in particular, to the pharmaceutical industry), strong outflow of foreign exchange in the form of dividend, profit, royalties and technical fees that every now and then aggravated chronic problems with balance of payments. Last but not least, an effort to break a dominant position of MNCs in some sectors played its part as well. The main idea behind all that was to make foreign companies contribute more to the economic development of India and to help domestic companies grow more rapidly by skewing overall conditions to their advantage.

The most vital changes were brought about by new Patent Act of 1970. Section 5 removed the patent protection on final products and instead it granted only the patent protection on the manufacturing processes. It reduced the time of patent protection from 16 years to 14 years. According to Shashi Sharma, the law left economy almost untouched with one exception – the pharmaceutical sector (Sharma 2007: 6). In case of the pharmaceutical sector the protection period was brought further down to five years (from the date of patent granting) or seven years (from the date of patent application). The act also stipulated that once the patent is granted to a specific pharmaceutical product, the production of the drug must be commenced within three years from the date of sealing a patent in India. In case of not performing in the way stipulated by the law, the local producers were automatically given the right to obtain a license from the patent holder for a royalty not exceeding 4 per cent of ex-factory price in bulk form (Lanjouw 1998: 51; Chaudhuri 2005: 36-38).

The law is alleged to have had a decisive impact on the pharmaceutical industry in years to come. It provided the notional “big push” and laid the foundations for the massive growth of Indian pharmaceutical firms. From now on, through reverse engineering which had required far less outlays on R&D, Indian firms came to challenge MNCs by bringing copycats of proprietary drugs onto the market at the fraction of costs while the same branded drugs were still under patent protection in the Western countries (Smith 2000: 13). Within two decades Indian companies built necessary

expertise and capabilities in drug manufacturing to effectively compete with MNCs. All that entailed the long-term decline of MNCs on the Indian pharmaceutical market (Bhatacharrya 2004: 372).

In India, the activity of all businesses was guided by a complex system of regulations and licenses that had to be obtained on every kind of economic activity ranging from imports, expansion of existing product lines, up to tapping new sources of profits through diversification into other business areas. Generally, foreign companies were hit more heavily than domestic companies to the extent that they were prohibited from taking up various business activities which were reserved only for Indian companies (Chaudhuri 2004: 164). As for import licenses, GOI primarily favoured domestic production against the import. However, if necessary, they gave preference to Indian companies over foreign ones. Towards the end of the 1970s there was certain relaxation in this area as other products were placed on the newly created "open general licenses" list. Although trade policy aimed to promote companies to export without exception, its real impact was rather adverse (Lall 1987: 26-27).

The trading licenses system was supplemented by a far more important system of industrial licenses through which GOI exerted control over investment flows and their target areas in the economy. The licences entitled companies to operate, to install production facilities up to the certain capacity level allowed by the licenses, to manufacture specific products, to import technology etc. In the pharmaceutical sector, licenses were meant to keep foreign companies in check from encroaching in product categories and areas of activity reserved for Indian public and private companies (Lall 1987: 30). Furthermore, this was complemented by a resolution which ruled out the possibility for MNCs to set up a production plant unless they manufacture basic chemicals and intermediaries, which were in short supply in India (Joseph 2009: 16).

In the 1970s GOI took decisive steps to clamp down on all MNCs (Thomas 2007: 19). In India, there was made a distinction between "foreign owned" and "foreign controlled" companies. The former was a business entity in which non-residents held a majority stake of over 51 per cent. If the company was qualified as "foreign controlled", the foreign equity ranged between 26 and 50 per cent (Dhar, Gopakumar 2007: 42). In 1973 GOI passed the bill called Foreign Exchange Regulation Act (FERA). The law required MNCs to bring the foreign stake down to 40%. The purpose of this Act was to gain control over the companies' operations and technology and to decrease remittances of capital in form of royalties, technical fees, "head-office expenses" etc. (Kumar 1990: 12-13). The consequence of FERA was that a clear line was drawn between those companies with foreign equity no more than 40% (treated as Indian companies) and, on the other hand, those with foreign equity in excess of 40% to be referred to as FERA companies. Provided MNCs fulfilled some preconditions

(high content of sophisticated technology employed in the production, output directed largely for export, majority production of bulk drugs as against formulations) the foreign equity was allowed to be as much as 74%. Yet, such companies had to deal with harsher treatment on the part of India's administration. Apart from general provisions, MNCs had to comply with a special clause for the pharmaceutical industry stipulating that FERA companies with the turnover of over Rs. 6 crore are required to earmark a certain percentage of sales for R&D (Chaudhuri 2004: 164).

Due to the poor economic performance at the beginning of 1980s, India hesitantly launched reforms that led to partial liberalization, de-licensing and deregulation, and pave the way for further changes in the system. India initiated simplification and rationalization of its trade policy; however, it did not intend to abandon its system of import licenses or to liberalize imports altogether. Nevertheless, there occurred some relaxation as to imported inputs for industry. To boost productivity, India facilitated, inter alia, import of capital goods for the purpose of modernization (Parikh 2006: 167-170). In hindsight, the reforms undertaken during the 1980s were not comprehensive enough to make an impact big enough to pull India out of the economic difficulties. The slow economic resurgence is mainly ascribed to the expansionary fiscal policy which, however, had fatal consequences at the beginning of the 1990s (OECD 2009: 20).

### *Industry-specific policy framework*

India reflected the importance of pharmaceutical industry by placing it into the category of "core" industries. Apart from general regulations, the sector was also governed by drug policy. The 1970s was a watershed as to the attitude of India towards the pharmaceutical sector. Tightening the regulation regime and exerting intervention appeared to have a serious impact for both segments of the pharmaceutical industry – MNCs and Indian companies. Yet, it appeared to have affected the former in much more serious way.

Upon the recommendations of the Hathi Committee of 1975, whose role was to reassess and redesign the policy towards the pharmaceutical and to come forward with new interventions for the sector, GOI came to reshape the industry, place it on the new foundations and enable local drug companies to grow. The main goal was to achieve self-sufficiency and self-reliance and to break up the monopolistic position of MNCs on the Indian market. The recommendations reflected themselves

in drawing up New Drug Policy (NDP) of 1978 and Drug Price Control Order (DPCO) of 1979. Both legislative measures affected heavily the profitability of the whole sector by setting ceiling prices for bulk drugs, and formulation process in order to keep them artificially low. Furthermore, GOI set the limits on rate of return from the business operations (Chaudhuri 2005: 309). Through NDP GOI discouraged MNCs presence in drug formulations or bulk drug lines of products involving unsophisticated basic technologies, leaving these product lines for domestic companies (Thomas 2007: 19).

GOI also began to systematically control drug prices, with first controls introduced in the mid 1960s. The purpose was to make drugs available at the affordable prices for the common population. Only since DPCO 1979 GOI was successful in checking their unwarranted price escalation. As in the previous legislation there was no fixed ceiling on the mark-ups, the drugs produced by MNCs yielded high profits as they managed to manipulate the final prices through inflated costs, e.g. by way of imported inputs. In fact, the drug policy set the prices in a way that it entirely reversed profitability of bulk drugs and formulations as was usual until then. The production of formulations had been more profitable up to that moment, while bulk drugs production became more important for MNCs' baseline afterwards (Chaudhuri 2005: 277-279). The other objective of DPCO was to create a system of incentives for domestic producers to begin manufacturing new formulations and using active ingredients in those drugs being products of original research in India. (Dhar, Gopakumar 2007: 69).

With reference to the FERA companies, the NDP 1978 required to dilute their equity share in case they had produced only formulations or had not applied "high technology" in the production of bulk drugs (Chaudhuri 2004: 164). To achieve their greater involvement in bulk drug production and to cut down the formulation output, NDP stipulated the ratio of controlled bulk drug to formulations to be at 1:5 for MNCs, whereas for local companies it was set at 1:10. As a consequence, MNCs were forced to focus more on production of costly bulk drugs if they wished to keep manufacturing of formulations at the same level as before. And they complied as is apparent from reports in order to preserve the level of formulations (Narayana 1984: 61).

Furthermore, as for the profitability level at companies with turnover higher than Rs. 6 crore per annum, as that applied predominantly to MNCs who were the only such big players in India, the margin of pre-tax profit as a percentage of sales was fixed between 8 and 12% depending on whether the company was engaged in manufacturing of basic drugs and undertook research activities or not (Johri 1983: 50).

During the 1980s, in spite of halfway economic liberalization, some of the provisions were made even stricter. On the bright side, the number of controlled drugs dropped from 347 to 142, nevertheless still regulating prices of 70% marketed drugs in India. In addition, permissible profit margins that were set by GOI were adjusted upwards; however, with no lasting effect for the pharmaceutical companies. GOI also partly loosened strict conditions in drug imports (Chaudhuri 2005: 303; Barnwal 2000: 85-86). However, it also had the seamy side which further made the operation of pharmaceutical MNCs in India quite difficult. The revised Drug Policy of 1986 brought down the ratio between bulk drugs and formulations from 1:5 to 1:4, thus making the drugs production at FERA companies even less profitable. Also, FERA companies were disallowed to embark on production of ninety-four drugs that were de-licensed in the 1980s (Chaudhuri 2004: 165). Changes in the 1980s did not show any positive effect in the sector. Quite the opposite. Profitability, measured as profit before tax as a percentage of sales, which was at 15,5% in 1970, was continuously falling down until the beginning of the 1990s when it touched the bottom of the 2% mark (Karandikar 1994: 69).

Despite all harsh measures, GOI provided pharmaceutical companies with generous systematic support to export. In DPCO of 1986 GOI afforded pharmaceutical companies a complete flexibility in production for export without having to seek an industrial license. In addition, these products were completely exempted from the application of DPCO regulations. MNCs involvement in export brought FERA companies one more additional benefit. FERA Act also sought to incentivize MNCs to export. Provided that a FERA company shipped a minimum of 60 per cent of its total production abroad, they were allowed to keep foreign stake up to 74 per cent. If it exported the total output it was entitled to be in full foreign ownership (Joseph 2009: 15).

One of the major achievements GOI booked had been that it managed to reduce dependence on imports of drugs from abroad. By means of industrial licensing schemes and import restrictions, GOI made especially MNCs to switch to inputs and raw products produced in India. With the view of enhancing domestic production and R&D capabilities, GOI imposed various limitations and duties on MNCs and, concurrently, discriminated them in favour of Indian companies. Over this period, the Indian pharmaceutical industry evolved from import dependence to self-reliance in the entire line of formulations and, at the same time, was able to meet 70 per cent of bulk drugs requirements sourced from largely Indian companies (Joseph 2009: 16). In the course of two decades until the beginning of the 1990s, the pharmaceutical industry underwent a period of the structural transformation when generic companies of Indian provenance emerged as a new power that had to

be count in. Many of the current challengers to the Big Pharma companies were established and consolidated their position during that time (Dhar, Gopakumar 2007: 42).

After getting the overall picture of the policy environment, the next part will deal with impacts of policies on the pharmaceutical industry in general and MNCs in particular.

### *Implications for pharmaceutical companies with a focus on MNCs*

At the beginning of the 1970s the situation in the pharmaceutical industry did not seem to be much different from the 1950s. In two decades MNCs built up its dominant presence to such an extent that they had a command of 70% of the whole market in India. Out of 66 pharmaceutical companies with foreign equity operating in India 34 companies had more than 50% foreign equity holding. If we also include those with 40 to 50% foreign share, then their number climbed up to 49 (Singh 1985: 105). Moreover, classified by retail sales on the Indian market, of the top 10 pharmaceutical companies only two companies were of Indian provenience. (Thomas 2007: 19)

According to available figures, since DPCO 1970 the profitability level of pharmaceutical MNCs began to fall. The slump in profitability was more evident at MNCs as compared to Indian companies. Due to a stricter regulatory regime, MNCs were banned from some product categories as specified in a drug policy. The Drug Policy of 1978 grouped drugs into three categories of which MNCs were allowed to only take on production of drugs in the last category, whereas Indian companies could produce articles out of any of three groups. The ratio between bulk drugs and formulations together with the new patent legislation were to be blamed for harming companies' bottom line (Barnwal 2000: 61-62). By emerging Indian generic companies using the method of reverse engineering, MNCs lost the advantage of the first-mover. While the process patent regime allowed Indian drug makers to invent alternative processes for manufacturing products that were under product patent in other jurisdictions, the shortening of the term of the patent protection discouraged MNCs to file for patents in India (Dhar, Gopakumar 2007: 21). Furthermore, MNCs responded to the situation by avoiding supplying India with newest proprietary drugs with a view to protecting their own business interests and asset (Fink 2001: 103).

Nevertheless, MNCs were active in inventing ways to cope with the stipulated production ratio between bulk drugs and formulations required by GOI. According to the analysis made by Sahu it appears that MNCs resorted to processing bulk drugs from intermediate stages, instead of producing

bulk drugs from much more technologically advanced basic stages. Consequently, they were able to meet the requirements. However, this statement does not detract from the fact that MNCs did not evade decreasing profit margins (Sahu 1998: 85). On the sample of the data for the nine biggest pharmaceutical MNCs[3] (measured by equity holding in 1977-78), published by Singh, the fluctuation in profits is clearly evident (Table 1 in Appendix). Although the profit before tax rose up from Rs. 1805.77 lakhs in 1970-71 to Rs. 2823.59 lakhs in 1977-78 for the sample of the pharmaceutical MNCs, retained earnings had not experienced the same growth trend. Its rise was rather moderate, growing from Rs. 368.84 lakhs to Rs. 503.35 lakhs for the specific period. Moreover there is evidence of decrease in retained earnings for years 1973-1976.

What most strikes the eye is the amount of dividends being repatriated. Regardless of the inconstant amount of profits which fluctuated over time, dividends repatriated from India showed a rising tendency. One of the explanations for that might be that in view of the limited chances of business growth, parent companies were likely to siphon off as much profits in form of dividends as possible from their Indian subsidiaries rather than leaving subsidiaries with profits for investment or other purposes. The repatriated sums of technical fees, royalties etc. were, in contrast to dividends, accounted for far lesser amount. This is explained to have been due to the ceilings that GOI placed on transfers of technical fees, royalties etc, whereas no limit was set on dividends transfer (Singh 1985: 242). MNCs sought to repatriate send all profits abroad, leaving their subsidiaries just with minimum profits to keep their facilities running.

The slackening profitability coupled with uncertain and harsh economic conditions had an impact on the rate of investment at MNCs. The issue of business investment is associated with the FERA legislation. With the new patent system in force and restraints on expansion for MNCs, MNCs were increasingly reluctant to plough back more into the business than required by GOI. That is not surprising considering the possibility of expropriation of gains from such an activity was imminent at that time. FERA restrictions on the control of ownership also were not very instrumental to moving MNCs to upgrade their production process. According to Fink, by the beginning of the 1990s only 16 out of 30 biggest pharmaceutical MNCs had undertaken some investment activities in India (Fink 2001: 103).

Coupled with the weak patent protection and controlled drug prices, MNCs were also not inclined to introduce their new products in India. In the situation when the possibility of expropriation of proprietary knowledge was very high, they preferred to keep a product portfolio consisted of simple and not up-to-date products. Moreover, MNCs limited themselves to manufacturing unsophisticated

[3] Glaxo, Hoechst, Merck Sharp & Dhome, Parke Davis, Pfizer, Roche. Sandoz, Warner Hindustan.

drugs such as vitamins (the case of Merck, who was the only producer of the E vitamin in India at that time, is the case in point. (The Eastern Pharmacist February 1982: 88)), cough preparations or painkillers (Indian Pharmaceutical Industry 2007: 48).

Neither were the conditions and environment conducive to R&D, which is expected to be the core activity of pharmaceutical companies. FERA, though, required companies with turnover higher than Rs. 6 crore to set up research facilities and to allocate a certain percentage of sales to R&D. However, owing to weak protection of intellectual property, MNCs were reluctant to embark on any kind of fundamental research activities at a large scale, even when India had a range of comparative advantages for this. Because of direct access to the corporate R&D pool in developed countries, MNC's subsidiaries, naturally, invested a considerably lower percentage of sales into R&D than their Indian counterparts. In doing so, they engaged primarily in non-essential research activities. Instead of developing entirely new drugs, they rather focused on process development or improvement and formulations research (Drabu 1986: 194). Thus, under the weak intellectual property right regime, they agreed to undertake research in way it could not harm their operations or cause a profit loss due to the leak of proprietary knowledge.

To avert the decreasing profitability and to improve bottom-line results, MNCs-affiliates responded in different ways. An extreme solution was to close down a subsidiary and to retreat from India altogether. That routinely happened in cases when a company rejected to comply with FERA Act provisions about dilution of foreign equity share. Suhrid-Geigy was one of those companies that chose to phase out the plant rather than diluted its share (Bhagat 1982: 68). Although FERA was drawn up in order to regulate the foreign sector, it virtually opened new opportunities for MNCs to diversify. Companies, which conformed to "indianization" and reduced the foreign share to 40% (classified as non-FERA companies), were treated on a par with local companies, which gave them a chance of taking on production of drug categories shut out for FERA companies (e.g. drugs that were reserved only for Indian private companies).

By contrast, the product portfolio change or extension for FERA companies was possible only if they applied high technology to the production process and strictly held to the ratio between bulk drugs and formulations (Johri 1983: 51). Another option for FERA companies was to expand into manufacturing of de-controlled drugs and this way to beef up the revenue level. Other alternative was to expand into non-associated product categories, such as agro- and industrial chemicals, cosmetics, toiletries, dyes and synthetic rubber, where MNCs could leverage their expertise and knowledge of chemical processes (Johri 1983: 53). That this option was quite widespread among MNCs is supported by available data revealing a significant rise in non-pharmaceutical sales for this

period. Despite the sharp drop-off in value in case of some companies (Duphar Interfran, East India, Organon etc.), the rate of growth, on average, was quite substantial closing to 100%, and for some companies even surpassed the 100% mark (Cynamid, Hoechst or Searle) (Table 2).

Although the general trend among companies was to optimize cost-profit and to adapt to the market conditions of India characterized by high costs due to the sheltered-market nature, the other way companies attempted to escape the trap of decreasing profits margins was to engage more in exports (Chopra 2003: 8). This strategy had its certain appeal to pharmaceutical companies since the exported drugs did not fall within the ambit of DPCO, thus profit charged through export was much higher than that on Indian market (Mittal 1993: 109). Although there are no available data as to how big proportion of production was aimed at export, there are evidences on hand that some of the companies were quite successful on the international market. Every year India awarded the best export performer in the pharmaceutical sector a prize which in most cases was obtained by MNCs as illustrated by Glaxo or Hoechst (The Eastern Pharmacist February 1982: 84).

The period spanning from the second half of the 1970s to the early 1990s, was a period during which the industry experienced structural transformation through the growth of the Indian generic industry. This occurred in a large measure as a result of the adoption of the Patents Act of 1970 and other pharmaceutical-related policies. Many of the current challengers to the Big Pharma companies arose and consolidated during that time (Dhar, Gopakumar 2007: 42).

# YEARS OF EXPANSION

# PHARMACEUTICAL INDUSTRY FROM 1991 UNTIL 2005

## *General economic environment*

Following partial reforms the situation aggravated to such an extent that there was a need for a thorough reform in the Indian economy, if it was to put on a proper footing. India's balance of payment problems at the end of 1980s and the beginning of 1990s was a sort of a trigger for setting the reform process in motion. On 24th July 1991 GOI announced the New Industrial Policy programme in which it committed itself to accomplishing liberalization and opening-up of the Indian economy.

The Government's aim was to pay more attention to competitive advantage and to steer development of economy in this direction. Reforms were to restore market forces which henceforth were to increase the rate of investment and business decision of companies and to establish India as an attractive place for conducting business. In effect, the reforms completely disassembled the system of industrial licenses and relaxed the excessive state's involvement of the state in the economy. In the area of trade, the quantitative limits on imported goods were removed in favour of tariffs which were, over time, substantially cut from 150% in 1991 down to 35% in 2001 (OECD 2008: 21).

As for foreign-based companies, they began to be treated on a par with Indian counterparts. The range of products which MNCs could have begun manufacturing was considerably extended. Foreign investors were permitted to hold a majority block of shares that enabled them to wield a strategic control over a company.[4] In addition, the approval procedure for investment was made markedly simpler. Starting from 1994 clearance to investment on the basis of automatic approval base was granted to every foreign investment proposals involving up to 51% foreign equity in fifty high priority sectors; in other nine industries affiliated to high priority sectors this threshold was set even higher at 74% (Singh 2007: 24-26). In 2000 the ceiling for automatic approval of investment was ultimately increased to 74 per cent and a year later the fully-owned foreign subsidiary was allowed to be set up in India (Joseph 2009: 39).

FERA companies were allowed to invest and sell fixed assets at the market price provided the proceeds are not transferred abroad. Moreover, they were further relieved of restraints on their non-priority business operations. New amendments embedded in the FERA Act also enabled MNCs to take up any business activities without any restrictions. India also declared reintroduction commonly used brand names that were banned earlier in the 1980s. That represented one of the most significant changes for MNCs which derives above-average profits from their "brand" names than it is the case of non-branded/generic companies. Hitherto Cadbury's or Glaxo were obliged to change their company's name into Hindustan Cocoa Products and Glindia, respectively. The provision of restoring brand names also applied to using trade-marks. Besides, FERA companies were no longer required to export part of their output and could fully focus on catering to the Indian market (Singh 2007: 24-28). In the end, the controversial FERA Act was repealed and replaced in 2000 by a far moderate legislation referred to as FEMA (Jha 2005: 17).

India made substantial changes to make the investment environment more stable and secure. In order to facilitate the flow of foreign investment and to provide India with access to the global

[4] A foreign company wields the strategic control over its subsidiary if it holds 60% or more of its equities.

markets and sophisticated technologies, GOI constituted two specialised investment promotion agencies. In 1996 India established Foreign Investment promotion Council, to which, three years later, it added Foreign Investment Implementation Authority (Singh 2007: 24-26). The investment environment became more secure for foreign investors at the moment when India began respecting international standards for investment. By becoming a member of Multilateral Investment Guarantee Agency (MIGA) in 1994, India also guaranteed foreign investors against non-commercial risks involving expropriation (Gakhar 2006: 81).

Moreover, becoming a member of newly established WTO India was required to comply with WTO norms (TRIPS Agreement) as far as the intellectual property rights were concerned. This brought changes regarding Indian intellectual property regime in train. WTO granted Indian a transition period 1995 -2005 within which GOI had to adapt its patent law to the international standards and to reintroduce a product patent component into its legislation (Rao 2007: 53). This happened in three steps through introducing two provisions in its Patents Act. Article 70.8 of the TRIPS agreement obliged India to provide "a means" by which product patent applications can be filled from 1st January 1995 (so-called "mailbox applications"). If the products in question included in the mailbox applications were granted a patent in any of the WTO member countries and the products had obtained marketing approval in any of the WTO member countries, then, according to Article 70.9, five-year exclusive marketing rights (EMRs) had to be granted by India before the patent on the product was either granted or rejected in India after 2005. Then, on 1st January 2000 a Second Amendment came into effect. It brought the existing Indian Patents Act in compliance with all substantive directives and regulations of the TRIPS Agreement, barring those related to the introduction of product patent provisions. The chief issues were re-defining patentable subject matter, extension of the term of patent protection to 20 years and amending the compulsory licensing system. Ultimately, on 1st January 2005, a third amendment was made to the Patents Act, whereby a full-fledged product patent regime was introduced to the areas extended to pharmaceuticals that were previously omitted from those provisions (Dhar/Gopakumar 2007: 6).

Despite that, by gradual moving towards product patent regime, GOI did not seek to endanger the position of local drug makers. GOI, hence, sought to exploit all flexibilities conferred to India in TRIPS Agreement. For example, in the case of mailbox applications, drugs that fell within this category were still allowed to be produced by Indian drug makers. Hence, the system of incentives assured Indian drug companies to go ahead with the production of imitated drugs of branded versions (Joseph 2009: 14). Following this general part, the next sub-chapter deals with policies related exclusively to the pharmaceutical industry.

*Industry-specific policy framework*

The impact of economic changes made itself felt in the drug industry slightly later than in other sectors. Only since the revision of Drug Policy in 1994 changes have become more evident in the pharmaceutical industry. Despite of taking over some of the basic objectives from the previous drug policy, the drug policy of 1994 was shaped in a way that already reflected changing environment and conditions. Main goals of the drug policy of 1994 was to ensure drugs to be accessible at affordable prices, to strengthen the quality control over drug manufacturing, to encourage the rational use of drugs, to create environment more conducive to investment into the pharmaceutical sector and to strengthen and upgrade local production facilities (Rao 2007: 51). In effect, the drug policy significantly liberalized criteria for drugs to be qualified for price controls. The licensing system for production of bulk drugs and formulations was completely dismantled barring just five types of drug[5] reserved for the public sector companies which were ultimately de-reserved by 1999 (Chaudhuri 2004: 165). This was an essential stimulus for companies to restructure their portfolios along the lines with the opportunities offered by the world and Indian markets (Joseph 2009: 3).

The amended DPCO of 1995 decontrolled those drugs for which were enough in the market to keep their prices down. As a result, the number of drugs under price control came down to 73 (sometimes is indicated 74[6]); however, the price control still affected 40% of drugs on the market. For the purpose of implementing and enforcing DPCO provisions, the GOI passed authority on to the National Pharmaceutical Pricing Authority (NPPA) established in 1997 (Sampath 2009: 16). The drug policy nevertheless made conditions for foreign investment in the pharmaceutical sector further liberal, stipulating that foreign shares of up to 51% were permitted in the manufacturing of all bulk drugs, intermediates and formulations. Applications for foreign shares above 51% were then assessed on the case by case basis. Apart from that, the law said that any company pursuing R&D activity was eligible to 100% tax holidays (Ray 2005: 158). Since 2004, the cap on the level of foreign share was completely lifted, which opened the sector to foreign investors (Gakhar 2006: 89).

In 2002 GOI issued an updated New Drug Policy in which it further lowered a number of drugs under control to 38 articles. The main objective was to encourage companies, mainly Indian, to allocate a

[5] Vitamin B1, Vitamin B2, Folic Acid, Tetracycline, Oxytetracycline
[6] Greene 2007: 3

larger proportion of profits into research and development. NDP set itself a task to prepare local companies for the post-2005 period when the new patent regime will come into force. Among other, NDP placed a great emphasis on strengthening the system of quality control over drugs and distribution and developing a set of incentives instrumental in directing investments in desirable areas (Indian Pharmaceutical Industry 2007: 71; Prasad 2008: 43).

During that time, India established itself as a rising pharmaceutical power. All along the way the process was facilitated by a set of advantages India boasts about. India attracted companies mostly for its low cost of fixed assets and human capital. It had competitive manufacturing facilities complying with the highest international standards of the US Food and Drug Administration. As compared to the US and Europe, the cost of building is about one-fourth. Apart from that, the cost of a laboratory analyst/chemist in India is between one-fifth and one-eighth of the cost in the US. The first-class scientists are very well trained, yet earn about a third of Western counterparts' salaries (Joseph 2009: 39). As far as production costs is concerned, they are estimated to be around 30-50 per cent lower than in developed countries.

### *The MNCs and Indian pharmaceutical companies*

At the beginning of market-oriented reforms in 1991, the picture of the pharmaceutical industry was dismal. The sector was showing one of the lowest profitability among all sectors in the Indian economy at that time. Despite being 70% self-sufficient in the category of bulk drugs and a net exporter of finished drugs, the share of pharmaceutical products accounted only for 3,8% of India's total manufactured exports could hardly produce any significant impact on the economy (Pradhan 2006: 7). However, the most striking feature of that time was the increasing supremacy of Indian companies over MNCs in the pharmaceutical sector. Building up expertise and capabilities under the conditions of a sheltered market in the 1970s and 1980s enabled Indian pharmaceutical companies to carve an unenviable mighty position in India. Strengthening its position reflected in increasing market share from 32% in 1970 to 77% in 2004. Correspondingly, the share of MNCs declined from 68% to 23% in the observed period (Thomas 2007: 19).

By 1994, MNCs commanded 38% of the market, whereas the domestic pharmaceutical companies accounted for 61%[7]. Breaking down the market into drug categories, MNCs controlled 30% of the

[7] The residual 1% was accounted for by two Indian public companies.

formulations market, 15% of the bulk drugs market and contributed with 15% to the pharmaceutical exports. The rest belonged to Indian companies (Ray 2005: 158).

Over the past two decades the Indian pharmaceutical industry developed a three-tier structure. The industry is composed of large private companies, which can be further divided into two categories, the one being subsidiaries of foreign firms and the other being of Indian provenance. Furthermore, there is a large fragmented group of small-scale firms. In terms of scale of business operations, the pharmaceutical sector is characterized as "long tailed", that is to say there is a relatively small number of large companies as compared to a large number of small pharmaceutical firms (Dhar, Gopakumar 2007: 42). The reason for that was evident. Due to the low capital requirement, small pharmaceutical companies mushroomed very fast reaching the mark of 20.000 units by the year 2005. Whereas globally the pharmaceutical sector is characterized by high degree of concentration where the market is split among a couple of large drug makers, in India the industry was one of the most fragmented pharmaceutical sectors of its kind in the world (Greene 2007: 4).

The sector is organised in three principal industrial associations: Organisation of Pharmaceutical Producers of India (OPPI) is an umbrella organisation for MNCs. Second main association was the Indian Pharmaceutical Alliance (IPA) that advocates interests of large Indian companies. The last one, Indian Drug Manufacturers Association (IDMA), is a representative body for small Indian drug companies (Sampath 2009: 16). Despite the fact that opening-up of the Indian economy and its integration into the global economy was largely perceived as a threat by many industries in India, for Indian pharmaceutical companies, which were traditionally more outward-oriented, it posed a window of opportunities (Dhar 2007: 50).

Indian companies have owed their immense growth to few contributory factors. Thanks to the less stringent intellectual property environment, they acquired a critical asset – reverse-engineering capabilities – in the relatively short span of time that they could deploy and build upon further in the 1990s. The less stringent intellectual property regime favoured Indian companies more than MNCs and acted as a catalyst for their rapid expansion. In the 1980s Indian companies grew mostly through trade with countries where intellectual property rights regime was similar in the set-up and rules of enforcement. That signifies that socialist countries with USSR being at the top were key trading partners for Indian pharmaceutical companies. Sheltered market, high trade barriers for foreign competitors and favourable economic policy worked as an enabler in this process. Thus, Indian companies were able to master technical skills and capabilities within a relatively short period of time. When a new age arrived for the Indian pharmaceutical companies in the 1990s, they were well-equipped to supply not only the local market, but also to succeed on lucrative and highly regulated

markets in the US and the EU. Great reputation in basic research and high quality technology and facilities attracted MNCs which entered into cooperative agreements with Indian drug makers and contracted out initial stages of R&D process to them (Joseph 2009: 19).

Dismantling burdensome policies towards the pharmaceutical industry demonstrated itself positively in the increasing profitability of the sector as it is apparent from the observation of selected sample of both MNCs and Indian companies for which data are available. Soon the sector became the leading one in the economy as far as profitability is concerned (Dhar, Gopakumar 2007: 50).

Due to the progressive integration of Indian firms in the global pharmaceutical industry, increased modularization of the pharmaceutical R&D globally and outsourcing possibilities, Indian drug sector underwent an overhaul in the 1990s and emerged in the new configuration fit for the new period. It was part and parcel of trends in global health care which had already been underway. Rising costs of drugs development, pressure on the price-cutting along with changes along the supply chain only further accelerated this process and forced global drug makers to change their business models in order to maintain the bottom-line in order. Indian pharmaceutical companies seized the opportunity and managed to establish themselves in niche markets (e.g. as contract manufacturers or researchers). Their business model has been based on a two-pronged collaborator-competitor strategy. Indian companies sought to disrupt global patterns of innovation through introducing knockoff versions of branded drugs that are cheaper, affordable and, in some cases such as HIV/AIDS drugs, targeted towards the mass market. The economies of scale achieved thanks to the production of cheaper low-end drugs for the mass market provided them benefits that high-value added production lines could not bestow. Indian drug makers were enabled to maintain diversified portfolios of products due to a stable and strong domestic market demand that secured them a strong source of income. Besides tapping the low-cost, low-risk and medium returns overseas generic markets helped them to secure income that were ploughed back into the areas of new chemical entities, novel drug delivery systems, as well as improvements of the available drugs like lowering side-effects or different dosage forms. (Chadha 2006: 2). Apart from that they entered into cooperation with MNCs to work jointly on R&D projects on a wide range of diseases, including global ones. Indian companies successfully diversified their portfolios between regulated and unregulated markets to achieve economies of scale (Sampath 2009: 29).

With the introduction of the above mentioned liberal measurements, pharmaceutical MNCs again turned their attention to India. Were, however, MNCs indeed so quick to take up the first opportunity to invest in their Indian subsidiaries or did they rather choose a more cautious approach? Available figures on gross fixed assets (hereafter GFA) (Table 3) reveals that the latter is

more likely to be the case. Despite the steadily growing interest in India, it must be pointed out, that in the first years after the initiation of the economic reforms MNCs hovered around and waited to see what next the development would bring in. Such a stance on the part of MNCs is quite understandable as no-one was able to tell whether the relaxed economic conditions were not just an intermezzo before the screw would be tightened up again. This uncertainty made MNCs hesitant to get fully engaged in India. According to figures of GFA for the ten biggest MNCs in India[8] (measured by sales in 2005), there is evident only slow growth for years 1991-2005, though there were differences among companies. On one hand, the biggest expansion in GFA was recorded by AstraZeneca, which raised fixed assets more than ten times, from Rs. 6.32 crore in 1991 to Rs. 68.13 crore. Besides, the biggest MNCs subsidiary by GFA in 2005 became Aventis Pharma reaching up to Rs. 277,00 crore. On the other hand, Novartis recorded almost nil growth during the observed period. Although in the latter case, the amount of the gross fixed assets surged until 1996 when it began continuously falling. By the year 2005, measured by GFA, the biggest companies were GlaxoSmithKline, Pfizer and Merck having Rs. 263,7 crore, Rs. 139,4 crore and Rs. 116,9 crore, respectively.

For some of the MNCs, there was a slight decrease in fixed assets for some years, the most noticeable at Aventis where GFA declined between 1998 and 2002 to that extent that by 2005 it did not manage to reach its pre-1998 level. Similar trend was evident at GlaxoSmithKline (hereafter GSK) where the drop was recorded between 2002 and 2005. Another case is Pfizer. The reason for that was thought to be that during that time MNCs were more or less prudential in the investment activities in their subsidiaries. If they invested, as suggested by Smith (Smith 2000: 12), it was predominantly into existing capacities rather than seeking entirely new investment ventures. MNCs carried with themselves a burden of over-capacity from the past that was a result of the prescribed ratio between bulk drugs and formulations as discussed above. Now, as claimed by Chaudhuri, some of them took steps to scale down excessive production capacities and divest themselves of these redundant capacities. That consequently led to de-investing their Indian operations in favour of more pharmaceutical imports (Chaudhuri 2005: 139).

Yet, comparing the data of MNCs with those for the five biggest Indian pharmaceutical companies[9], reveals a sharp difference. As Indian drug makers began at much lower level as for GFA, they witnessed more robust double-digit growth. Out of all Indian drug makers, Dr. Reddy's Laboratories' (henceforth DRL) GFA magnified most, expanding through 2005 90-times from the baseline in 1990.

[8] Abbott India Ltd., AstraZeneca Pharma India Ltd., Aventis Pharma Ltd., Fulford (India) Ltd., GlaxoSmithKline Pharmaceuticals Ltd., Merck Ltd., Novartis India Ltd., Organon (India) Ltd., Pfizer Ltd., Wyeth Ltd.

[9] Aurobindo Pharma Ltd., Cipla Ltd., Dr. Reddy's Laboratories Ltd., Piramal Healthcare Ltd., Ranbaxy Laboratories Ltd.

Translated into absolute terms, GFA rose from 11,72 Rs. crore to 1064 Rs. crore. Although figures for GFA might look impressive for Indian drug companies, it is not sufficient to provide us with an overall picture. By standards of "Big Pharma", Indian companies stood no comparison with them and were regarded as dwarfs in most areas such as sales, investment and R&D spending.

Besides increasing more or less GFA, MNCs also took steps to secure a position within their subsidiaries by consolidating and raising its equity share. Now that MNCs were no longer bounded by restrictions of FERA Act, they increased the equity share so as to ensure controlling power there. MNCs raised their equity shares at a much faster rate during the period after the year 2000 in comparison to the second half of the 1990s. The case in point is Aventis, which successfully consolidated its position to emerge as the largest pharmaceutical foreign firm in India in 2005 in terms of GFA (277 Rs. crore), closely followed by GlaxoSmithKline (Dhar, Gopakumar 2007: 44).

According to research on the book value of Indian pharmaceutical companies done by Dhar and Gopakumar, it is obvious that a majority of Indian pharmaceutical companies were in good financial shape in the 1990s. This points out to the fact that during this period Indian pharmaceutical companies were consistently profitable piling up the cash which translated into their high book value. Some companies, such as DRL and Cipla, chalked up very high rates of growth of net worth during 1995-2005. By contrast, the largest company, measured by sales, among the Indian firms, Ranbaxy Laboratories, did not maintain the comparable trend of increase in the market value. Measured in terms of the absolute value of net worth, Ranbaxy Laboratories was by far the largest Indian pharmaceutical firm during the entire period 1995-2006. But as stated by Dhar and Gopakumar, DRL and Cipla were catching up rapidly with the leader (Dhar, Gopakumar 2007: 44).

The favourable business conditions in India and demographical changes in the society affected to a great extent the sales strategies of MNCs as demonstrated by figures for sales for the period 1991 and 2005 (Table 4). The market penetration, based on sales growth data, gives evidence of a strong position of generic manufacturers in the Indian pharmaceutical industry during 1995 – 2006 as against MNCs. In terms of sales growth registered by leading drug makers, Indian generic firms performed much better than MNCs and by far outstripped their foreign rivals in terms of sales value. Sales grew at a modest rate throughout the 1990s, yet picking up towards the end of the 1990s. Out of the sample of 15 foreign drug companies a half of them saw single-digit growth, whereas Novartis suffered even a decline in total sales. This trend reached a turning point around the year 2000 when the sales began moving steeply upwards (Dhar, Gopakumar 2007: 44-45). MNCs have built up particularly strong presence in the segment of sophisticated drugs, such as vaccine, for which they possessed required expertiser and capacities to produce them. With the new patent system on the

horizon, MNCs, such as Wyeth, GSK, Sanofi-Aventis or Eli-Lilli, launched a vast array of innovative products in India in the ensuing years (Joseph 2009: 26).

Looking on the sales record of the sample companies, in 1991 the top sellers among MNCs were GSK, Aventis, Novartis and Pfizer, whose sales exceeded the mark of 100 Rs. crore. At the end of the observed period, in 2005, the list looked more or less same. GSK bagged the top spot selling goods in value of 1593,86 Rs. crore. The second and third rank was occupied by Aventis and Pfizer, with sales accounting for 868,47 Rs. crore and 684,83 Rs. crore, respectively.

Indian companies bounced off in 1991 from the similar base line as MNCs. At the beginning of the 1990s Ranbaxy Laboratories, Cipla, Piramal Healthcare and DRL counted among the best perfomers in terms of sale. Yet, in contrast to MNCs, in the following years they achieved much greater rate of growth on the sales front. When in 2005 only GSK posted sales over 1000 Rs. crore, in the sample of Indian companies, all of them (5) had sales record larger than 1000 Rs. crore, with Ranbaxy having more than 3800 Rs. crore.

Different performance on part of MNCs and Indian companies are further underlined by CAGR indicator. The sales grew fastest at AstraZeneca with 17,48% annually between 1991 and 2005, followed by Pfizer (13,71%) and Abbot India (11,91 %). These figures were eclipsed by what can be observed at Indian drugmakers. There, average annual growth in sales between 1991 and 2005 was around 20% and more. The “worst” record had, surprisingly, Ranbaxy Laboratories with 19,90% change over year. On the other end was Aurobindo Pharma (31,13%) and DRL (27,68%).

Sales records of Indian companies stood in the stark contrast to those of MNCs. Indian companies owe the upturn in their sales much to the development on the side of the global markets where generic medicines became a highly demanded article. That is ascribed to the fact that developing countries increasingly turned their attention to generic medicines as a suitable alternative to patented drug categories which were out of reach for most of them due to high prices (Dhar, Gopakumar 2007: 57). Indian strategy of focusing on high-quality generic drugs began bearing fruit. They managed to squeeze out MNCs from the top spots of the “sales” ranking list in India and were recording success also in other less developed countries. Whereas in 1995 five of the top ten pharmaceutical firms (in terms of sales revenue) were MNCs, in 2004 only GSK remained on the best-selling-drug companies ranking list. Despite facing uncertainties resulting from dismantling the process patent regime following India’s accession to the WTO, Indian generic companies navigated successfully through this period and established themselves as a power to count on (Dhar,

Gopakumar 2007: 43). It is no surprise that India began to be labelled as “the pharmacy of the developing world”.

However, during the 1990s Indian pharmaceutical companies came to refocusing the sales strategies. Apart from supplying domestic and other “low priced-high volumes” markets in Asia, Africa and Latin America, they also increasingly zeroed in on regulated markets in the U.S. and Europe where companies could record much higher profit margins. Intensive overseas focus came about in part due to a stagnant Indian market and vigorous competition among branded generic producers (Rai 2003). Capitalizing on more than two decades of reverse-engineering experience, low-cost production and a large number of state-of-the-art manufacturing meeting strict norms of the US Food and Drug Administration benefited Indian companies in getting a foothold in regulated markets (Joseph 2009: 4-5).

Foreign trade strategies are quite illustrative of different approaches MNCs and Indian generic drug makers employed in this area. Since the 1990s MNCs preferred to regain a market share back from Indian rivals to engaging Indian subsidiaries in exports. Due to lack of appropriate time line data for exports, data from the FOB category is used for this part (Table 5). FOB is a trade term meaning “Free On Board” which indicates price of goods plus services of loading those goods on a vessel at the port of departure. For most of the MNCs exports represented quite a negligible part on their balance sheets mostly ranging between 1% and 10% of total income. Yet, there existed few exceptions as evidenced by Aventis which markedly departed from this general line. In 1991 the company shipped around 18 per cent of its output from India. Despite, fluctuations in its export performance, this share went up to 22 per cent by 2005. According to data, the low level of exports indicates that companies unfold the potential of their production capacities to satisfy demand on Indian market rather than directing output for exports. That was particularly pronounced for big players such as GSK and Pfizer, whose exports to total sales showed decreasing tendency since 2000. This implies that the global pharmaceutical majors did not have any intention of turning their production facilities in India into manufacturing hubs for the global markets (Dhar 2007: 51).

Conversely, as for imports, there is no convincing evidence that would support the statement that MNCs would import more to India due to removed trade barriers. Based on data from the Prowess database (Table 6), the ratio of the value of imported goods to the value of total sales was calculated for the purpose of elucidating the role of imports played in this set-up. The results showed that the ratio was quite miniscule for MNCs, which means that they did not pursue a strategy of importing finished drugs to India. Only in case of Organon, Merck and Novartis this ratio was as much as 10% and above in the observed period after 2000, with the highest figure accounted for by Novartis –

over 14%. Fulford, on the contrary, cannot be taken into account at this place as data lines for this company are quite fragmentary. As a result, findings refute the statement made earlier by Chaudhuri and Greene that with falling import barriers MNCs would resort to importing drugs from abroad rather than producing them in India. However, it would be very useful at this point to have a detailed breakdown of imports to see the structure of drug imports to India. It could further shed light on the sale strategy of MNCs as to product line-up shipped from abroad and marketed in India. However, available data do not provide such a deep insight in the situation.

Turning attention to the aspect of revenues, its modest growth on the side of MNCs is likely to have had a few reasons. First, MNCs lacked the proper knowledge of Indian market and did not have established market channels as their Indian counterparts to reach to as a large part of the population as possible. The second reason, and more important, is associated with the marketing strategy of MNCs. Despite the low income level, India emerged over time as an expanding and promising market. The purchasing power of the middle class has continuously been growing stronger and its purchasing habits show remarkable signs of convergence with the global trends. They are willing and able to buy expensive branded drugs (Smith 2000: 20). Moreover, changing disease profiles with a large share of global diseases, including life-style related, already prevalent in the country along with privatisation of health care coupled with the boom in specialised clinics and treatment centres represented fantastic market opportunities for prospective investors (Sampath 2009: 7). Realizing the potential of this top-end market, MNCs were increasingly geared to it, as evidenced by Pfizer. Pfizer's market strategy in India was back then focused on a few low volume high-priced bulk drugs that are supplemented by several off-patent formulations which match Indian disease pattern (Ray 2005: 164-165). Furthermore, some companies bet on promotion of branded generic products. And as evidenced by Novartis, this strategy proved to work (India Pharmaceuticals 2005: 24). Even though India was a net exporter of pharmaceuticals, as far as life-saving and new generation on-patent drugs are concerned, India was still thrown back on the MNCs. As the import of these drug categories is duty free, MNCs are in a good position to capitalize on that (Greene 2007: 17). No doubt, the rising demand for both lifestyle-related drugs and other was the driving force of all growth in the Indian pharmaceutical sector in the past and coming years (Sampath 2009: 8).

By way of illustration, the trend in revenues was completely different at Indian pharmaceutical companies. For a majority of Indian companies, export markets stood higher on their agenda than domestic markets and accordingly, their focus corresponded to that. They were incomparably more export oriented than their MNCs counterparts. Measured by export intensity (exports to the sales turnover), DRL was a front-runner in this regard with over 10% in 1989 and blazing the trail onwards.

In 2004 the value amounted to above 55%. The same statement can be made about Ranbaxy Laboratories and Aurobindo Pharma, where the ratio went up from 30% to 71% between 1991 and 2005 and 7,81% to 47,74%, respectively. On the other hand, Piramal Healthcare was a glaring exception for which the ratio was never more than 10% for the observed period.

According to Joseph, the export performance of Indian companies indicated gains from the economies of scale and diversification in key markets. Ranbaxy and DRL had set the trend of focusing on regulated markets showing that winning the 180-day period of marketing exclusivity to sell as first their generics in the US market was a lucrative option worth pursuing. Even when firms do not gain the 180-day period of marketing exclusivity, a simple entry onto the US market brings in large benefits due to the price competitiveness of Indian generics (Joseph 2009: 23-24).

By removing restrictive policies and regulations in the 1990s, the overall profitability of the pharmaceutical sector has surged up. That was evident especially in the case of MNCs. In the view of the profitability ratio, measured as a ratio of the profit before tax to total income (Table 7), it is apparent that that during the first half of the 1990s the profitability growth was rather modest and oscillating. However, towards the end of the 1990s the profitability of MNCs began to show two-digit growth. Yet there are examples of MNCs whose profitability were in the order of two-digit for the whole observed period. For example, Wyeth's profitability was constantly on the rise growing by two-digit from 1991. Whereas, for the others, such as Pfizer, the profitability ratio was incomparably low. Interestingly, with only few exceptions, MNCs profitability was lagging behind that of Indian counterparts through the 1990s. This trend was reversed as late as before 2005 when most of the MNCs demonstrated better profitability data than their Indian counterparts. However, Cipla, for example, constantly recorded high level of profitability ranging from 19% to 24% and bore favourable comparison with MNCs in this respect. Nevertheless, it must be noted that profitability fluctuated to a great degree on case to case basis for both streams of companies. Rising profitability entails that companies would have more available cash for investment, especially in R&D. However, as the following part reveals rising profitability did not, correspondingly, translate into higher allocations into R&D.

The pharmaceutical industry is regarded to be a heavily knowledge-based sector. R&D in the Indian pharmaceutical industry has two outstanding features. First, the pharmaceutical industry was seen as by far the biggest R&D contributor of all sectors in India. Second, the level of R&D spending was steadily on the rise among drug companies. Yet, approaches towards R&D were then completely diverse in MNCs, on one hand, and Indian companies, on the other hand. What is particularly striking is the fact that incomparably higher profitability of pharmaceutical companies as against those from

other sectors did not automatically lead to higher expenses in R&D. To illustrate varying R&D allocation intensity of both streams of pharmaceutical companies, this part of research draws on R&D ratio measured as a percentage of R&D costs to total sales (Table 8) for the period of 1989 to 2005.

In spite of rising profitability, MNCs did not accordingly allocate a corresponding bulk of funds into research activities. Most MNCs from the sample of companies invested less than one per cent of sales in R&D. As for some companies, the trend in R&D spending was rather retrograde as exemplified by AstraZeneca and Aventis. Whereas in 1994 these two companies allocated around 4% and 3% of sales to R&D, respectively, this share dropped down to 1,10% and 0,46% of sales, respectively, by 2005. And they were no exceptions. The only MNC where investments in R&D were stable in the course of years was Pfizer, who kept the level of investment to R&D at 3% of its revenue. The major reason for modest R&D activities on part of MNCs was due to the weak and imperfect intellectual property right environment. MNCs subsidiaries preferred to leave groundbreaking basic research to parent companies in the developed countries. In India, they rather followed the path of incremental improvements of existing products and processes in order to achieve either greater benefits or productivity and output (Ray 2007: 167).

One of the sources of great profits comes from patented drugs which were marketed at higher prices than generic versions in order to allow innovative drug makers to recoup the costs. Western drug makers attempted to secure a monopoly over drugs through secondary patents that would extend the lifetime of patent protection. As a consequence, many of them launched their own branded generic product lines. Another way to fend off competitive pressures from generic drug makers was to unleash long and costly legal battles against their generic competitors. As regards risks and returns associated with a patent challenge, there were significant differences in stakes between originators and generic pharmaceutical companies. From the originator's point of view, the patent litigation proved to be a high return-zero risk strategy, as they would gain greatly even by delaying the entry of a generic challenger by a few months. For generic pharmaceutical companies, on the contrary, it is a high return-high risk strategy. They are in the position to gain a lot if they manage to win the trial, but also to lose a lot in case of failing (Thomas 2007: 29).

R&D strategies of MNCs stood in the sharp contrast to trends at Indian pharmaceutical companies. The R&D profile of Indian drug makers experienced major changes through 2005. The most noticeable of these was the manifold increase in spending on R&D that was recorded since the onset of the 1990s. Over time they were increasingly allocating much higher percentage of sales into R&D compared to MNCs, with Dr. Reddy's Laboratories (DRL) and Ranbaxy investing as much as 12% of

revenues in the key year 2005. Embracing R&D was a response to upcoming changes in the Indian patent law, because it was the only way for Indian drug makers to keep the pace with future and protect their business. Let us turn the attention to what preceded this trend. In the 1990s a gradual shift began to occur regarding R&D. It was increasingly evident that Indian companies will not be able to thrive merely on the back of process research and imitate proprietary drugs without getting more involved in basic research. Hence, there was seen more concentrated efforts to fund and to upgrade their R&D capabilities and facilities in order to manoeuvre themselves into innovative R&D (Prasad 2008: 35).

There are four specific areas which Indian pharmaceutical companies concentrated their research on – generic drugs, novel drug delivery system (NDDS), new processes development and new drug discovery. Indian pharmaceutical companies, generally, employed an approach, which was quite different to what MNCs pursued. For the most part of the 1990s, they were engaged in research on entirely new drug molecules. But instead of bringing them into later stages which involved long, costly and risky period of trials, they rather licensed them out to their MNCs rivals which had the necessary financial and expertise strengths to bring them further to the next stage. Clinching deals with MNCs helped Indian companies to secure cash flow that was used to keep their R&D department in motion and to propel their R&D and structural transformation. As a part of this strategy, Indian pharmaceutical firms were carrying out research on global diseases that have been largely neglected by research departments of global drug companies and which perfectly fit to MNCs portfolios. The seamy side was that research focus of Indian generic companies was deflected from neglected diseases prevalent in the Third world countries, in general, and in India, in particular, towards more common diseases in the developed world (Thomas 2007: 27).

Additionally, Indian pharmaceutical companies were also heavily involved in novel drug delivery system since it required less time and capital expenses to roll out some marketable products in the short term. By way of illustration, developing a new way of delivering a drug to the body could take somewhere between 3 to 4 years with initial investment of about 20 to 50 million USD. Indian generic companies earned great respect for achievements in the field of NDDS which helped them open up new opportunities for collaboration with major pharmaceutical players for them (Dhar, Gopakumar 2007: 61-62).

The R&D of Indian drug makers can be split into two groups – generic-related R&D and proprietary R&D. Among Indian companies the lines separating generics and proprietary R&D was a very fluid one because they have historically tended to invest in R&D activities related to the production of generics. In the run-up to new TRIPS-compliant patent act, the dominant business model was one

where Indian drug makers focused on retaining generic product pipelines and just extended it into innovative categories of NDDS. After 2000 a new practice of spinning off an R&D department into separate business entity proliferated making the division between "generic R&D" and new drug discovery more explicit (Sampath 2009: 7). Three major factors help to elucidate the growing separation of R&D and generic activities in the Indian pharmaceutical sector. Generic products and proprietary R&D have both different product cycles: generics are less risky taking only about 2-4 years to get a marketable product. Proprietary R&D, on the other hand, is the capital intensive process taking up as much as fifteen years with a high degree of uncertainty whether the outcome will be successful. Indian investors were used to the generic mode of investment. First, firms operating within this model find it increasingly difficult to raise finance for their proprietary R&D activities; hence separating the operations and potential investors make it easier for them to operate. Second, huge R&D investment has reduced market capitalization of big firms, which in turn has affected their aspirations to go international. Finally, Indian firms have been both collaborators and competitors for the pharmaceutical majors. Collaborative research deals reached with MNCs were common practices for Indian drug makers, which allowed them to co-operate on the phase III and IV clinical trials, which only few Indian drug companies could finance and carry out in-house. Spinning off R&D arms into separate companies, according to the representatives from the sector, helped to create trust with global drug companies for collaborations on product development (Sampath 2009: 25).

R&D spending and activities by large companies proved to have a spread-effect on other companies as medium-sized generic companies soon followed suit. According to Dhar and Gopakumar, the mid-sized Indian pharmaceutical companies such as Glenmark Pharmaceutical and Torrent Pharmaceuticals were among the highest spenders on R&D (Dhar, Gopakumar 2007: 53-54). Still, if compared with the global R&D standards, Indian generic companies were considerably lagging behind global pharmaceutical majors, who ploughed about 20% of net sales back into R&D.

The corporate strategies as for research and development remained as varied as Indian pharmaceutical companies themselves. Several top Indian firms continued to be purely generic entities. For instance, Aurobindo, the fourth largest firm in the market, was a strictly generic company. Formerly it was producing bulk drugs only later to add also formulations to its portfolio selling bulk of its production on export. Aurobindo had then a very large R&D department; however it was still mostly involved in generics R&D. The same is valid for Cipla which is a well-known generic company for its drugs against HIV/AIDS. Other firms like Dr. Reddy's pursued a mixed strategy based on generics and new drug discovery through varied models. Drawing close to the critical year 2005

Indian companies have substantially beefed up allocation of funds to R&D activities. At that time, none of the existing Indian pharmaceutical companies possessed the necessary skills or resources to embark on the full-fledged process of a new drug discovery. Despite the fact that a large share of R&D spending was still devoted to developing novel drug delivery systems (NDDS), non-infringing processes, and similar activities that came within the category of generics, there were signs that some of the leading Indian drug makers were set to develop greater innovative capabilities built upon synergies created in the past in order to get integrated faster into the global pharmaceutical industry (Thomas 2007: 24).

It is important to note that considerable differences in R&D spending among the top Indian firms were closely associated with their strategies in regard to product portfolios, export orientation and presence or (absence) of a vision to emerge as a pure R&D-based company. By way of illustration, the biggest R&D contributors were those firms which were largely oriented towards export. Available figures reveal that the steepest rise in R&D expenses over the period of 1993 to 2005 were recorded at DRL where it increased from 1,16% in 1993 up to 13,80% in 2005. The second to DRL in terms of R&D expenses was Ranbaxy Laboratories with 2,64% and 12,17%, respectively, which exported 64-70% of its total production. However, the top contributors seem to be an exception to the rule. If we take a thorough look at the pharmaceutical sector as a whole, the R&D intensity of companies gets negligible as one goes down the ranking list (Sampath 2009: 24).

# CONCLUSION

The analysis showed how the shifting institutional framework affected business operations of companies, particularly MNCs, of the pharmaceutical industry in India and in which way these companies responded to challenges emerging in the wake of institutional changes.

Today's success story of the Indian pharmaceutical industry is an outcome of the development of the past 50 years. During that time the institutional framework in which pharmaceutical companies conducted business developed between two kind of opposing poles, one characterized by restrictive regulatory environment and, the other being rather liberal and open economic environment, respectively. The economic environment of the pre-1970s period was characterised by quite welcoming attitude towards MNCs. India was well aware of its drug shortages, lack of expertise and capacities in the realm of drug production. Therefore, it established the business environment that

was favourable to foreign investment and MNCs through which it hoped to develop local pharmaceutical capacities and capabilities within a country. Over time as it became more evident that it fell short of expectations, GOI made a u-turn at the end of the 1960s and tightened the regime to the detriment of MNCs. Period of adverse economic policies for MNCs of the 1970s and 1980s proved, on the contrary, blessing for Indian companies who took advantage of the then conditions. Indian drug majors of today date their origins back to that period. MNCs were, in general, exposed to a harsher treatment from GOI than Indian companies and more burdensome provisions and regulations were applied to them. During those two decades GOI by way of various measures effectively broke dominance of MNCs and put in place policies that enabled local companies grow and develop research skills by copying proprietary knowledge embedded in branded drugs. However, this economic strategy of India proved to be unsustainable at the end of the 1980s and worsening balance of payment only precipitated the need for reforms and economic openness of the country.

Since the 1970s India successfully accomplished structural transformation of its pharmaceutical sector and laid the foundation for the rise of Indian generic pharmaceutical companies. By way of changes in legislation related to patents, pricing, drug policy, and foreign investment, GOI created an exclusive environment in the 1970s and the 1980s that greatly favoured local companies and enabled them to flourish to that extent MNCs were not allowed to. Controlling almost every area of business operations by GOI entailed that companies could pursue business and row only within strictly bounded environment. All along the way, GOI attempted to steer MNCs in a way that brought as many benefits to India as possible. In its effort, GOI, for instance, prescribed MNCs to be involved in costly and technology-intensive parts of manufacturing and drug research and development where India lacked sufficient expertise, technology or necessary resources. GOI's measures, virtually, brought down the overall profitability of the pharmaceutical sector and created an atmosphere of unpredictability regarding intellectual property rights, thus reducing incentives to invest, carry out drug research and development and expand business in general. As for MNCs, their main concern was how to effectively protect their intellectual property or rather how not to endanger advances of their R&D activities. And, second, how to maintain bottom line results given the restrictive price cap on certain drugs categories. With this in view, all activities spanning investment, R&D, sales were subordinated to.

New competition from generic drugs in the 1970s and the 1980s, along with drug price controls, uncertainty ownership rights, imperfect patent regime and interference by GOI in drug companies operations (e.g. stipulating bulk drugs-formulation ratios) led to decreasing profits among MNCs which further decreased investment into fixed asset and new drug research. In order to avoid sinking

profitability, MNCs branched out into related as well as non-related lines of production like fertilizers or cosmetics, where they could leverage and capitalize on its expertise from drug manufacturing or tried to manufacture drugs which did not fell in the scope of the drug price control. The adverse business environment in India in general further moved MNCs to keep rather low profile or to completely withdraw from India.

Those MNCs who decided to stay in India largely refrained from marketing portfolios of cutting edge medical products and rather specialised in an off-patent drug portfolio. Given uncertain economic conditions and limited chances to charge high prices on drugs, parent companies preferred to drain away a majority of available profits from their Indian subsidiaries. This occurred mainly through the transfer of dividends, as no ceiling, unlike on licensing and technical fees etc., was put on dividend payments.

Thanks to few far-reaching legislative changes pertaining to patents, drug policies and foreign investment, that turned the tables on MNCs, Indian drug makers increasingly benefited from those conditions and thrived at the expense of MNCs. Indian pharmaceutical companies were able to take roots in the 1970s, consolidated over the 1980s and emerged as rivals to MNCs at the beginning of the 1990s. As a result of that, the market share of MNCs vis-à-vis Indian drug companies continually diminished whereas Indian companies strengthened their presence in the Indian market throughout 2000. Another striking feature was that the past development resulted in the pharmaceutical industry of India becoming the most fragmented pharmaceutical sector in the world, composed of a small number of major drug players, both foreign and Indian, and a countless number of small local companies. India owes its rise to the pharmaceutical hub to reverse-engineering expertise, modern production facilities, low personal and assets costs coupled with a large pool of English-speaking scientific talent.

Nevertheless, the economic system of India proved to be inefficient and unsustainable towards the end of the 1980s. The lacklustre economic growth was achieved at the expenses of mounting indebtedness and problems with the balance of payments. This ushered in sweeping economic reforms in the 1990s. The positive effects of economic reforms were not immediately visible in the pharmaceutical industry.

During the period from 1991 until 2005, trends with MNCs, on one hand, and Indian drug makers, on the other, followed different paths. Contrary to expectations, with the economic liberalization, MNCs did not invest and expand their subsidiaries as much as Indian companies did. Oddly enough, measured by the rise in gross fixed assets, the effects of the economic liberalization did not translate

into greater investment activities. The uncertainty about the future direction in the economy prevailed among MNCs subsidiaries which preferred to stay clear of any major investment projects. That explains their rather modest increase of gross fixed assets. On the other hand, neither can it be spoken of de-investment since the value of gross fixed assets among MNCs continually increased over time, though with fluctuations. The MNCs "rise" was rather overshadowed by and was put in a stark contrast to what was happening on the side of Indian pharmaceutical companies, where the investment boom was truly massive. Their rate of growth was at two-digits annually and Indian drug makers grew vigorously for the observed period. Nevertheless, by standards of pharmaceutical majors, Indian pharmaceutical companies were rather small.

Economic liberalization accompanied by demographical changes provided a considerable boost to pharmaceutical sales which was clearly shown on balance sheets of both foreign as well as Indian drug makers. Yet, Indian companies far outperformed MNCs in this regard too. In the course of the 1990s sales grew slightly moderately; however, they began soaring up at the turn of the century. The slow start on the side of MNCs can be attributed to the uncertain environment in regards to intellectual property rights. In the situation when imitation of drugs was a legal tool of Indian drug makers, MNCs shun away from marketing portfolios of their newest (and expensive) drug. Segment-wise, MNCs commanded a strong position in complex drugs like vaccine due to their refined and advanced expertise in drug development and production.

More modest sales for majority of MNCs in comparison with Indian rivals are attributed to underdeveloped market channels and relative unawareness of the local market conditions and habits. The only exception to the rule is GSK, which is a company with the longest tradition of conducting business in India. Despite all adverse conditions MNCs faced in India in the past, GSK did not discontinue its business activities and thanks to a deep knowledge of conditions in the Indian market, GSK became one of the top 10 biggest pharmaceutical companies in India measured by the size of the market share. Indian drug makers, on the contrary, were aimed at high-quality off-patent drugs by which they also won markets overseas. Gradually, the term "pharmacy of the world" became a common name for the Indian pharmaceutical industry that was predominantly represented by companies of Indian origin.

Furthermore, the available data do not support claims that MNC would have embarked heavily on the importation of drugs into India instead of producing them locally. This strategy pursued by MNCs back in the 1950s and the 1960s did not see revival. However, some of the MNCs indeed imported quite a high volume of pharmaceutical products to India. But taken as part of the total sales, it represented a small portion and never reached a higher scale. Given the low share of imports on

total sales, it is reasoned that MNCs must have modernized production facilities to satisfy the growing demand in India from local manufacturing lines.

Indian drug makers were much more export oriented than MNCs subsidiaries in India. The reason is clear since MNCs sought to strengthen its position in the Indian market and did not intend to turn their Indian subsidiaries into manufacturing hubs supplying the rest of the world. Instead, they made efforts to use more of their existing production facilities more for catering the Indian market where they saw a tremendous untapped potential.

On the other hand, Indian companies were to a far greater extent focused on export partly due to a fierce competition in respective market segments that squeezed margins. Other factor that plays a role in their expanding was that overseas markets were far more profitable than the Indian one. As a result, Indian companies, particularly after 2000, shipped a majority of their production abroad.

An increasing export focus entailed a qualitative change with Indian drug companies. In order to export to highly regulated markets in developed countries, Indian companies had to comply with a diverse set of strict requirements concerning manufacturing and sourcing processes. By meeting regulatory standards, they upgraded their facilities to the Western standards and thereby becoming attractive partners for MNCs to collaborate with.

Relaxing price controls and a decreasing number of drugs falling within the scope of a price control entailed rising profitability in the whole pharmaceutical sector. A noteworthy feature of the pharmaceutical industry is that, in spite of the adverse development in the past, the sector continued to be the most profitable among all industries of the Indian economy. In the context of profitability, two distinctive phases are evident for the period 1991-2005. Through the 1990s the profitability ratio stood higher at Indian drug makers than at MNCs. This was the result of past heavy-handed regulations that weighed MNCs more down than Indian counterparts. In the second phase, from the end of the 1990s onwards, there was a clear reversal in profitability with MNCs posting higher profitability ratio and outperforming Indian companies in this respect. That was associated not only with more favourable economic environment, but chiefly with the forthcoming changes in the IP legislation. MNCs were in a better position to reap higher profits thanks to targeting such customer groups that could afford high-value drugs of the Western style. As a result, MNC's profitability records were higher than those for Indian companies.

Nevertheless, the uncertainty over the protection of intellectual properties and their effective enforcement in India acted as a drag on R&D. In that situation, MNCs subsidiaries deployed very limited amount of resources to R&D which, in the best cases, amounted to about 3% of total sales.

MNCs contributions to R&D at the global level, however, ranged between 16 and 20% of total revenue on average. The reason for this low percentage of sales allocated to R&D by MNCs was due to the strong R&D base in developed countries where they were based and where their major groundbreaking research was taking place. R&D department of MNCs subsidiaries in India were rather engaged in delivering incremental improvements in drug efficiencies or the way they are administered to patients rather than in innovative research. Indian drug makers, on the contrary, earmarked a greater part of their budget for R&D because of the anticipated new patent law. Indian companies were well aware of the fact that their business model based on mere copying branded drugs would not be a sustainable path for the company's growth in the future and, hence, if they wanted to survive under new conditions, they had to invest more in building up additional scientific expertise and capabilities. Still, the extent of R&D involvement was determined by the overall strategy of a company, whether it zeroed in on international or local markets. It is generally true that companies, focussing more on highly regulated markets, usually contributed comparably more than those with local focus.

Nevertheless, it must be noted that in spite of up and downs, the pharmaceutical industry of India grew into enormous prominence and played an important part in the global pharmaceutical industry set-up. Even though, the playing field for MNCs in India is far from being perfect and on equal footing vis-à-vis Indian drug makers, the potential of Indian market was too big lure to leave it altogether.

# APPENDIX

**Table 1**

| Profit appropriation by pharmaceutical MNCs (1970/71-1977/78) (Rs. Lakhs) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Year** | **Profit before tax** | | **Profit after tax** | | **Dividends** | | **Retained Earnings** | | **Dividends as % of PAT** |
| | Total | % +/- | Total | % +/- | Total | % +/- | Total | % +/- | |
| 1970-71 | 1805,77 | - | 730,34 | - | 367,50 | - | 368,84 | - | 50,32 |
| 1971-72 | 1743,86 | -3,43 | 796,18 | 0,01 | 366,78 | -0,2 | 429,40 | 18,34 | 46,07 |
| 1972-73 | 1993,30 | 14,30 | 871,90 | 9,51 | 390,54 | 6,48 | 481,36 | 12,10 | 44,79 |
| 1973-74 | 1990,50 | -0,14 | 782,88 | -10,21 | 445,96 | 14,19 | 336,92 | -30,01 | 56,96 |
| 1974-75 | 1699,70 | -14,61 | 722,18 | -7,75 | 307,78 | -30,98 | 414,40 | 23,00 | 42,62 |
| 1975-76 | 1147,55 | -32,48 | 658,71 | -8,79 | 461,75 | 50,02 | 196,98 | 52,47 | 70,00 |
| 1976-77 | 2427,05 | 111,50 | 884,54 | 34,28 | 499,40 | 8,16 | 385,14 | 95,52 | 56,46 |
| 1977-78 | 2823,59 | 16,34 | 1102,85 | 24,68 | 600,00 | 20,14 | 503,35 | 30,69 | 54,40 |

Source: Singh 1985

**Table 2**

Non-pharmaceuticals sales, 1977-82 (Rs. lakhs)

| **Name of the company** | **1977-78** | **1978-79** | **1979-80** | **1980-81** | **1981-82** |
|---|---|---|---|---|---|
| Cynamid | 423,07 | 487,70 | 572,32 | 613,29 | 864,37 |
| Duphar Interfran | 150,27 | 166,42 | 101,42 | 79,97 | 80,93 |
| East India | 31,11 | 33,97 | 39,32 | 34,71 | 3,74 |
| German Remedies | 1,97 | 3,64 | 4,48 | 7,00 | 3,84 |
| Geoffrey Manners | 729,54 | 851,11 | 1067,73 | 1172,89 | 1336,64 |
| Glaxo | 1698,08 | 2110,58 | 2044,96 | 2427,74 | 3022,84 |
| Hoechst | 224,50 | 129,60 | 376,60 | 562,30 | 705,40 |
| Organon | 19,25 | 0,57 | 0,84 | 0,71 | 1,18 |
| Pfizer | 23,84 | 27,62 | 36,34 | 40,86 | 38,27 |
| Ranbaxy (IN) | - | - | 24,65 | 53,94 | 197,35 |
| Richardson Hindustan | 7,99 | 9,16 | 12,69 | 7,59 | 11,14 |
| Warner-Hindustan | 31,88 | 40,90 | 30,76 | 24,24 | 43,45 |
| Searle | 1,61 | 1,03 | 1,42 | 21,89 | 73,69 |
| Standard Pharma | - | - | - | - | - |
| Unichem (IN) | 14,59 | 36,36 | 10,42 | 5,30 | 12,19 |
| Bombay Drug House | 2,96 | 2,85 | 4,72 | - | - |
| Merck Sharp & Dohme | 28,74 | 59,13 | 45,73 | 30,58 | 8,98 |
| CIPLA (IN) | 10,78 | 12,82 | 14,30 | 13,08 | 12,99 |
| Aceto Chemicals | - | 0,68 | 0,21 | 0,46 | 0,49 |
| Fulford | 5,45 | 0,68 | 1,93 | 3,14 | 1,44 |
| MAC Lab. | 20,77 | 21,79 | 24,53 | 28,60 | 59,34 |
| Roussel | 35,00 | 115,00 | 205,00 | 297,00 | 352,00 |

Source: Narayana 1984

**Table 3**

Gross fixed assets, 1989-2005 (in Rs. crore)

| | 1989 | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Multinational companies** | | | | | | | | | | | | | | | | | |
| Abbott India Ltd. | 17,72 | 21,46 | 26,77 | 28,49 | 28,25 | 30,12 | 35,48 | 51,19 | 63,74 | 66,79 | 68,12 | 69,99 | 71,04 | 72,94 | 64,25 | 64,94 | 65,27 |
| AstraZeneca Pharma India Ltd. | 5,54 | 5,96 | 6,32 | 7,4 | 8,14 | 11,52 | 16,72 | 26,9 | 29,49 | 34,68 | 38,35 | 44,13 | 50,67 | 53,92 | 58,65 | 64,66 | 68,13 |
| Aventis Pharma Ltd. | 87,3 | 106,9 | 174,7 | 182,9 | 190,1 | 209,6 | 206,4 | 223,9 | 245,7 | 285 | 263,2 | 253,2 | 228,1 | 231,7 | 256 | 273,6 | 277 |
| Fulford (India) Ltd. | NA | 1,65 | 2,15 | 1,93 | 2,05 | 2,3 | 2,61 | 3,13 | 3,68 | 4,15 | 4,56 | 4,89 | 5,26 | 5,13 | 5,73 | 5,73 | 7,4 |
| GlaxoSmithKline Pharmaceuticals Ltd. | 101,8 | 125,2 | 142,4 | 160,5 | 177,3 | 0 | 194,1 | 182,3 | 194 | 211,7 | 224,2 | 248,5 | 259,8 | 322,6 | 275,3 | 263,3 | 263,7 |
| Merck Ltd. | 27,5 | 38,11 | 52,54 | 54,35 | 52,9 | 55,58 | 62,87 | 72,18 | 88,71 | 99,13 | 103,4 | 125,7 | 126,6 | 130,8 | 129,1 | 113,4 | 116,9 |
| Novartis India Ltd. | 65,39 | 70,89 | 87,27 | 113,6 | 131,8 | 163,5 | 168 | 196,5 | 179 | 176,4 | 197,2 | 197,4 | 150,8 | 151,8 | 155,9 | 90,64 | 87,67 |
| Organon (India) Ltd. | 6,99 | 7,33 | 7,75 | 8,25 | 9,02 | 9,71 | 10,72 | 12,39 | 14,3 | 17,97 | 21,15 | 26,09 | 34,36 | 33,65 | 33,48 | 36,87 | 17,16 |
| Pfizer Ltd. | NA | 27,83 | 30,47 | 32,87 | 50,47 | 55,58 | 61,03 | 65,06 | 55,61 | 66,69 | 74,26 | 79,66 | 87,98 | 82,81 | 142,3 | 125,4 | 139,4 |
| Wyeth Ltd. | 18,54 | 19,28 | 22,06 | 23,52 | 25,46 | 28,08 | 29,42 | 31,17 | 32,01 | 45,27 | 49,55 | 50,34 | 49,64 | 97,15 | 114,2 | 114,5 | 88,37 |
| **Indian companies** | | | | | | | | | | | | | | | | | |
| Aurobindo Pharma Ltd. | 0 | 0 | 0 | 0 | 1,83 | 2,73 | 11,06 | 34,45 | 45,12 | 59,98 | 102,2 | 154,8 | 209,1 | 275,1 | 494,4 | 696,4 | 923 |
| Cipla Ltd. | 26,35 | 42,7 | 51,19 | 63,26 | 78,27 | 104,7 | 124,1 | 139,4 | 159,6 | 183,8 | 216,5 | 246,1 | 287,9 | 420,6 | 545,8 | 796,8 | 1093 |
| Dr. Reddy's Laboratories Ltd. | 0 | 11,72 | 15,56 | 21,44 | 35,97 | 44,98 | 71,46 | 99,67 | 121,9 | 144,5 | 217,9 | 242,3 | 519,9 | 617,6 | 736,5 | 916,2 | 1064 |
| Piramal Healthcare Ltd. | 7,2 | 9,41 | 38,77 | 61,7 | 77,45 | 103 | 153,8 | 229,2 | 468,9 | 568,2 | 216,3 | 275,5 | 302,5 | 393,8 | 422,2 | 660,2 | 854 |
| Ranbaxy Laboratories Ltd. | 48,83 | 50,77 | 73,13 | 119,1 | 167,3 | 220,6 | 329,2 | 460 | 584,8 | 805,5 | 869,3 | 924,2 | 927,8 | 1045 | 1247 | 1667 | 2232 |

Source: CMIE, Prowess database

**TABLE 4**

Sales, 1991-2005 (in Rs. crore)

| | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 14 Yr CAGR |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Multinational companies** | | | | | | | | | | | | | | | | |
| Abbott India Ltd. | 97,62 | 118,15 | 147,07 | 175,18 | 208,24 | 264,85 | 278,33 | 299,17 | 329,95 | 382,43 | 372,36 | 425,58 | 446,78 | 474,01 | 471,69 | 11,91 |
| AstraZeneca Pharma India Ltd. | 25,84 | 29,76 | 37,65 | 43,76 | 54,69 | 65 | 77,93 | 99,2 | 101,35 | 107,38 | 71,92 | 153,2 | 196,11 | 210,89 | 246,42 | 17,48 |
| Aventis Pharma Ltd. | 302,32 | 275,27 | 293,88 | 363,46 | 310,63 | 356,26 | 410,98 | 565,12 | 534,96 | 419,37 | 598,03 | 669,14 | 709,68 | 793,56 | 868,47 | 7,83 |
| Fulford (India) Ltd. | 55,29 | 68,66 | 77,83 | 86,13 | 92,52 | 97,36 | 112,6 | 128,29 | 122,7 | 134,49 | 140,41 | 94,7 | 130,51 | 131,79 | 151,97 | 7,49 |
| GlaxoSmithKline Pharmaceuticals Ltd. | 416,42 | 493,77 | 554,23 | 788,73 | 920,16 | 706,34 | 762,41 | 879,51 | 903,08 | 952,01 | 1120,17 | 1167,89 | 1209,5 | 1490,89 | 1593,86 | 10,06 |
| Merck Ltd. | 96,52 | 120,05 | 121,72 | 152,29 | 176,86 | 206,11 | 223,1 | 260,84 | 279,8 | 315,95 | 341,65 | 385,56 | 404,06 | 418,39 | 438,09 | 11,41 |
| Novartis India Ltd. | 273,53 | 335.89 | 393,73 | 440,73 | 469,32 | 516,06 | 619,51 | 680,68 | 765,99 | 845,2 | 457,74 | 481,72 | 488,29 | 523,1 | 490,09 | 4,25 |
| Organon (India) Ltd. | 52,99 | 51,5 | 59,7 | 68,38 | 81,65 | 95,3 | 99,09 | 95,2 | 146,51 | 150,67 | 175,81 | 188,87 | 180,99 | 160,66 | 190,97 | 9,59 |
| Pfizer Ltd. | 119,84 | 140,54 | 171,27 | 213,84 | 244,19 | 256,88 | 167,2 | 267,9 | 333,99 | 374,49 | 410,33 | 696,74 | 588,4 | 684,83 | 724,15 | 13,71 |
| Wyeth Ltd. | 74,66 | 100,51 | 114,54 | 130,12 | 135,01 | 150,48 | 165,77 | 219,51 | 255,58 | 261,87 | 297,01 | 307,88 | 335,77 | 351,88 | 289,92 | 10,18 |
| **Indian companies** | | | | | | | | | | | | | | | | |
| Aurobindo Pharma Ltd. | 0 | 0 | 26,13 | 38,67 | 86,27 | 121,76 | 221,89 | 295,73 | 550,24 | 745,77 | 1000,64 | 1038,47 | 1192,74 | 1341,37 | 1161,83 | 31,13 |
| Cipla Ltd. | 123,64 | 151,4 | 199,03 | 245,57 | 298,71 | 362,36 | 452,58 | 515,92 | 623,64 | 771,65 | 1063,72 | 1400,72 | 1572,98 | 2055,66 | 2401,17 | 23,60 |
| Dr. Reddy's Laboratories Ltd. | 53,55 | 106,05 | 133,34 | 174,72 | 197,58 | 220,76 | 250,08 | 331,66 | 425,86 | 494,61 | 997,28 | 1611,33 | 1607 | 1755,15 | 1637,95 | 27,68 |
| Piramal Healthcare Ltd. | 58,73 | 83,62 | 89,51 | 124,35 | 155,89 | 185,37 | 503,58 | 534,64 | 441,79 | 489,71 | 574,63 | 960,8 | 1153,92 | 1444,51 | 1309,61 | 24,83 |
| Ranbaxy Laboratories Ltd. | 258,78 | 339,69 | 462,22 | 594,47 | 713,92 | 894,01 | 1042,73 | 1129,65 | 1667,03 | 1775,71 | 1959,78 | 3131,76 | 3888,98 | 3865,87 | 3284,03 | 19,90 |

Source: CMIE, Prowess database

**Table 5**

Ratio export (FOB)/sales, 1989-2005 (in %)

| | 1989 | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Multinational companies** | | | | | | | | | | | | | | | | | |
| Abbott India Ltd. | 1,60 | 0,79 | 1,54 | 3,64 | 1,04 | 0,96 | 0,44 | 0,03 | 0 | 0,27 | 1,03 | 0,75 | 0,87 | 0,39 | 0,35 | 0,44 | 0,59 |
| AstraZeneca Pharma India Ltd. | 2,54 | 1,93 | 2,32 | 1,01 | 4,36 | 7,68 | 10,00 | 9,40 | 2,53 | 2,33 | 0,94 | 0,75 | 0,25 | NA | NA | NA | 0,46 |
| Aventis Pharma Ltd. | 11,11 | 15,91 | 18,15 | 11,18 | 4,07 | 8,53 | 12,70 | 16,12 | 19,95 | 20,06 | 12,25 | 17,03 | 7,52 | 15,37 | 18,03 | 18,02 | 22,21 |
| Fulford (India) Ltd. | N/A | 8,56 | 4,97 | 5,82 | 0,01 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0,10 | 0 |
| GlaxoSmithKline Pharmaceuticals Ltd. | 2,24 | 2,22 | 2,92 | 2,98 | 2,55 | 0 | 2,17 | 3,63 | 3,22 | 5,05 | 7,19 | 7,80 | 6,45 | 6,33 | 4,80 | 2,30 | 1,78 |
| Merck Ltd. | 2,70 | 4,78 | 8,04 | 4,86 | 7,08 | 2,93 | 4,01 | 4,33 | 4,32 | 4,90 | 4,74 | 4,41 | 4,52 | 2,73 | 2,40 | 3,78 | 2,86 |
| Novartis India Ltd. | 5,81 | 5,16 | 4,85 | 6,98 | 3,25 | 5,08 | 8,29 | 12,63 | 11,68 | 11,04 | 6,63 | 6,75 | 3,01 | 1,11 | 1,11 | 1,43 | 1,83 |
| Organon (India) Ltd. | 14,13 | 29,94 | 27,36 | 17,79 | 7,89 | 9,70 | 9,77 | 7,04 | 8,61 | 8,24 | 8,78 | 10,65 | 4,60 | 4,11 | 10,76 | 13,59 | 6,99 |
| Pfizer Ltd. | N/A | 1,58 | 1,44 | 1,69 | 2,45 | 2,50 | 1,77 | 1,09 | 1,88 | 1,47 | 2,11 | 1,79 | 0,59 | 1,02 | 0,98 | 1,22 | 0,52 |
| Wyeth Ltd. | 1,57 | 5,97 | 5,38 | 14,80 | 5,82 | 1,76 | 1,06 | 1,10 | 1,10 | 6,01 | 6,76 | 8,65 | 9,46 | 11,76 | 7,46 | 6,70 | 0,03 |
| **Indian companies** | | | | | | | | | | | | | | | | | |
| Aurobindo Pharma Ltd. | 0 | 0 | 0 | 0 | 7,81 | 26,61 | 29,18 | 39,63 | 40,81 | 31,78 | 39,18 | 49,26 | 54,45 | 56,85 | 47,26 | 47,86 | 47,74 |
| Cipla Ltd. | 8,76 | 11,99 | 7,68 | 11,73 | 10,04 | 9,80 | 10,36 | 10,96 | 13,63 | 14,11 | 18,66 | 18,23 | 24,38 | 35,28 | 35,98 | 39,51 | 43,86 |
| Dr. Reddy's Laboratories Ltd. | 10,21 | 15,35 | 14,84 | 18,75 | 23,73 | 32,19 | 31,84 | 28,02 | 33,68 | 27,81 | 26,41 | 43,08 | 57,43 | 57,20 | 55,92 | 55,79 | N/A |
| Piramal Healthcare Ltd. | 3,20 | 0 | 0,43 | 0,85 | 0,54 | 2,60 | 5,88 | 3,53 | 8,00 | 5,38 | 0,67 | 0,50 | 0,14 | 0,76 | 3,43 | 6,72 | 9,64 |
| Ranbaxy Laboratories Ltd. | 0 | 17,88 | 22,29 | 27,10 | 29,61 | 36,51 | 41,50 | 44,68 | 48,71 | 37,78 | 25,60 | 40,91 | 38,42 | 30,99 | 45,64 | 60,69 | 71,10 |

Source: CMIE, Prowess database

**TABLE 6**

Ratio import/sales, 1989-2005 (in %)

| | 1989 | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Multinational companies** | | | | | | | | | | | | | | | | | |
| Abbott India Ltd. | 0 | 0 | 0 | 0,27 | 0,41 | 1,43 | 0,009 | 0 | 0 | 0,21 | 0,09 | 0,25 | 0,35 | 0,30 | 0,76 | 1,89 | 1,79 |
| AstraZeneca Pharma India Ltd. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Aventis Pharma Ltd. | 0 | 0 | 2,61 | 1,59 | 1,56 | 1,78 | 1,72 | 3,04 | 0,81 | 3,12 | 5,29 | 0 | 4,09 | 4,17 | 8,41 | 5,11 | 0,11 |
| Fulford (India) Ltd. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 20,39 |
| GlaxoSmithKline Pharmaceuticals Ltd. | 0,66 | 0,97 | 1,74 | 0,44 | 0 | 0 | 0,21 | 0,10 | 0,23 | 0,82 | 0,70 | 0,96 | 1,11 | 4,87 | 3,57 | 2,67 | 3,67 |
| Merck Ltd. | 0 | 0 | 0 | 0 | 1,50 | 1,77 | 3,32 | 5,43 | 5,75 | 4,32 | 6,94 | 7,46 | 9,06 | 8,13 | 10,39 | 7,78 | 9,12 |
| Novartis India Ltd. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 6,05 | 6,31 | 7,63 | 8,90 | 11,61 | 11,61 | 18,37 | 12,34 | 14,13 |
| Organon (India) Ltd. | 0 | 2,52 | 4,51 | 8,31 | 8,34 | 4,72 | 7,52 | 10,84 | 11,52 | 15,35 | 9,97 | 14,11 | 10,65 | 9,67 | 8,04 | 8,18 | 9,82 |
| Pfizer Ltd. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0,22 | 2,72 | 1,77 | 2,68 | 2,67 | 3,13 | 2,25 | 3,09 | 2,08 | 1,07 |
| Wyeth Ltd. | 0 | 0 | 0,07 | 0,11 | 0,12 | 0,15 | 0,22 | 0,51 | 1,23 | 2,25 | 3,68 | 3,85 | 4,85 | 3,90 | 3,38 | 2,21 | 2,69 |

Source: CMIE, Prowess database

**TABLE 7**

Profitability ratio: profit before tax/total income, 1989-2005 (in %)

| | 1989 | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Multinational companies** | | | | | | | | | | | | | | | | | |
| Abbott India Ltd. | 9,66 | 9,84 | 9,71 | 8,88 | 7,26 | 7,69 | 3,02 | 7,35 | 10,81 | 21,88 | 10,98 | 20,85 | 19,52 | 17,05 | 19,03 | 20,98 | 26,04 |
| AstraZeneca Pharma India Ltd. | 8,07 | 7,1 | 10,7 | 5,87 | 5,91 | 9,86 | 15,61 | 12,97 | 14,78 | 17,15 | 15,88 | 18,37 | 17,41 | 6,83 | 12,25 | 19,34 | 20,78 |
| Aventis Pharma Ltd. | 1,95 | 3,66 | 2,58 | 1,64 | 1,79 | 6,18 | 9,17 | 8,05 | 8,22 | 7,83 | 5,05 | 8,03 | 8,04 | 14,88 | 13,15 | 19,59 | 26,76 |
| Fulford (India) Ltd. | 4,55 | 4,78 | 2,78 | 1,66 | 2,72 | 3,23 | 3,07 | 3,37 | 3,8 | 4,25 | 4,77 | -2,33 | 0,5 | 1,11 | -7,59 | 5,25 | 14,64 |
| GlaxoSmithKline Pharmaceuticals Ltd. | 7,53 | 6,21 | 3,9 | 2,08 | 3,65 | NA | 5,45 | 22,98 | 11,54 | 9,15 | 13,09 | 11,07 | 10,35 | 7,51 | 13,39 | 21,19 | 29,05 |
| Merck Ltd. | 5,65 | 5,41 | 2,68 | -1,58 | 1,39 | 3,98 | 9,67 | 12,16 | 12,89 | 13,03 | 13,88 | 9,99 | 16,68 | 18,38 | 15,69 | 16,13 | 24,89 |
| Novartis India Ltd. | 9,32 | 9,75 | 9,9 | 9,32 | 7,75 | 7,53 | 23,49 | 8,68 | 5,76 | 9,84 | 14,96 | 18,5 | 14,24 | 18,49 | 17,22 | 23,73 | 17,63 |
| Organon (India) Ltd. | 8,2 | 5,93 | 7,14 | 7,93 | 7,46 | 8,32 | 8,74 | 8,74 | 9,21 | 9,1 | 7,64 | 9,39 | 11,19 | 14,25 | 16,92 | 11,32 | 13,2 |
| Pfizer Ltd. | 4 | 5,52 | 5,28 | 2,5 | 4,55 | 8,15 | 4,91 | 7,17 | 10,1 | 13,26 | 8,08 | 15,78 | 16,98 | 18,51 | 17,42 | 7,28 | 10,61 |
| Wyeth Ltd. | 2,48 | 9,88 | 11,45 | 11,04 | 11,47 | 13,91 | 16,67 | 14,73 | 15,92 | 15,96 | 14,23 | 16,04 | 16,94 | 20,02 | 14,17 | 20,14 | 12,24 |
| **Indian companies** | | | | | | | | | | | | | | | | | |
| Aurobindo Pharma Ltd. | 0 | 0 | 0 | 0 | 10,71 | 8,25 | 7,18 | 6,03 | 6,57 | 8,68 | 10,01 | 10,92 | 8,28 | 8,25 | 11,5 | 12,65 | 3,65 |
| Cipla Ltd. | 7,04 | 6,89 | 8,75 | 8,41 | 7,35 | 7,71 | 11,18 | 10,15 | 21,5 | 24,3 | 23,94 | 21,82 | 21,88 | 19,73 | 19,54 | 18,33 | 20,73 |
| Dr. Reddy's Laboratories Ltd. | 0 | 0,65 | 5,9 | 12,28 | 18,33 | 17,81 | 20,03 | 21,37 | 13,94 | 15,91 | 13,76 | 13,37 | 17,42 | 29,64 | 26,22 | 16,65 | 2,59 |
| Piramal Healthcare Ltd. | 9,34 | 11,9 | 11,35 | 9,91 | 12,71 | 13,41 | 16,22 | 15,65 | 5,79 | 5,82 | 10,53 | 10,06 | 12,1 | 7,21 | 10,58 | 13,37 | 14,34 |
| Ranbaxy Laboratories Ltd. | 1,69 | 2,59 | 4,61 | 4,71 | 7,64 | 10,84 | 16,46 | 16,8 | 16,68 | 14,05 | 9,94 | 11,74 | 10,32 | 13,89 | 17,63 | 23,62 | 15,81 |

Source: CMIE, Prowess database

**Table 8**

Research and development, 1989-2005 (as % of sales)

| | 1989 | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Multinational companies** | | | | | | | | | | | | | | | | | |
| Abbott India Ltd. | 0 | 0 | 0 | 0 | 0 | 1,10 | 0,37 | 0,28 | 1,24 | 0,53 | 0,51 | 0,52 | 0,61 | 0,47 | 0,47 | 0,31 | 0,31 |
| AstraZeneca Pharma India Ltd. | 0 | 0 | 0 | 0 | 0 | 2,26 | 3,99 | 2,35 | 1,45 | 2,19 | 3,76 | 2,63 | 0 | 3,00 | 1,41 | 1,21 | 1,10 |
| Aventis Pharma Ltd. | 0 | 0 | 0 | 0 | 0 | 2,39 | 2,99 | 2,58 | 3,14 | 2,07 | 2,25 | 1,13 | 0,25 | 0,45 | 0,65 | 0,50 | 0,46 |
| Fulford (India) Ltd. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| GlaxoSmithKline Pharmaceuticals Ltd. | 0 | 0,50 | 0,74 | 0,68 | 0,58 | 0,43 | 0,58 | 0,69 | 0,41 | 0,34 | 0,48 | 0,47 | 0,37 | 0,34 | 0,32 | 0,24 | 0,28 |
| Merck Ltd. | 0 | 0 | 0 | 0 | 0,26 | 0,26 | 0,23 | 0,05 | 0,09 | 0,10 | 0,18 | 0,21 | 0,19 | 0,18 | 0,09 | 0,03 | 0,07 |
| Novartis India Ltd. | 0 | 0 | 0 | 0 | 0,34 | 0,47 | 0 | 0,28 | 0,62 | 0,75 | 0,57 | 0,71 | 1,47 | 0,34 | 0,12 | 0,19 | 0,19 |
| Organon (India) Ltd. | 0 | 0 | 0 | 0 | 0 | 0,15 | 0,76 | 0,51 | 0,27 | 0,29 | 0,08 | 0,12 | 0 | 0 | 0 | 0 | 0 |
| Pfizer Ltd. | 0 | 0 | 1,84 | 1,01 | 0 | 0,49 | 0,81 | 0,86 | 1,27 | 1,68 | 2,51 | 3,60 | 3,47 | 1,90 | 3,16 | 3,09 | 3,25 |
| Wyeth Ltd. | 0 | 0 | 0 | 0 | 0 | 0,57 | 0,42 | 0,53 | 0,42 | 0,48 | 0,62 | 0,46 | 0,37 | 0,38 | 0,32 | 0,48 | 0,19 |
| **Indian companies** | | | | | | | | | | | | | | | | | |
| Aurobindo Pharma Ltd. | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1,43 | 0,83 | 1,08 | 1,64 | 4,22 |
| Cipla Ltd. | 0 | 0 | 0 | 0 | 0 | 0,03 | 2,68 | 0,02 | 0 | 3,16 | 3,32 | 3,11 | 2,82 | 2,92 | 2,97 | 0 | 2,35 |
| Dr. Reddy's Laboratories Ltd. | 0 | 0 | 0 | 0 | 1,16 | 1,70 | 1,79 | 1,80 | 2,14 | 2,36 | 1,66 | 1,90 | 1,33 | 2,58 | 6,33 | 9,31 | 13,80 |
| Piramal Healthcare Ltd. | 0 | 0 | 0 | 0 | 0 | 0 | 0,17 | 0,19 | 0,04 | 1,05 | 0 | 5,02 | 1,61 | 1,06 | 1,77 | 1,28 | 4,27 |
| Ranbaxy Laboratories Ltd. | 0 | 0 | 0 | 0 | 0 | 2,64 | 4,90 | 4,09 | 4,39 | 4,41 | 2,74 | 3,12 | 3,74 | 2,46 | 4,94 | 7,14 | 12,17 |

Source: CMIE, Prowess database

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- Speciality: Industrial policies, economic development, international affairs of Africa, South America and Asia
- Visiting student at the **University of California, Santa Barbara, United States (Sep – Dec 2010)**
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- **M.Sc. , London School of Economics, London, United Kingdom (2009 – 2010)**
- Speciality: Analysis of the course of modern economic growth; industrial clusters, economic development of North America and Europe, industrial development policies of South America and Asia

**2005 – 2009** **B.A. in International Area Studies, Institute of International Relations, Charles University, Prague**

- Speciality: International trade, foreign direct investment, political, economic and social issues of the European Union and German-speaking countries
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- Specialization: Small- and medium-sized enterprises in Germany, institutional framework of the European Union, international trade regimes

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## WORK EXPERIENCE

**Aug – Oct 2012** **AIM – European Brands Association**, Brussels, Belgium **/ *Research Assistant***

- Undertook market and industry analysis concerning the branded goods industry in Europe
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**Apr – Jul 2012** **Directorate-General for Enterprise and Industry, European Commission**, Brussels, Belgium / ***Trainee*** - *Industrial Competitiveness Policy Unit*

- Contributed to the staff working document on industrial competitiveness policy, produced a chapter on R&D intensity
- Researched macro-economic and industry structure data covering a broad range of sectors (e.g. automotive; pharmaceuticals; manufacturing; fast moving consumer goods)

**Jul – Dec 2011** **Business, Investment and Technology Services Branch, United Nations Industrial Development Organization**, Vienna, Austria / Intern

- Conceptualized and developed a project on business-to-business partnerships
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