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Abstract

The Indian pharmaceutical industry ever since its inception, has been deeply affected by a large variety of institutional factors and policies, ranging from patents, foreign exchange regulations, price controls, industrial licensing and organization of research and development in the public and private sectors. This paper considers the causes and implications of reforms and changes in the policy framework, particularly in terms of technological capability, technology sourcing, knowledge transfer and local production in the Indian pharmaceutical industry. The analysis of the complex web of policy reforms since the 1940s and its influence on technology evolution at the firm and industry level in India in this paper emphasises the subtle relationship between public policy and technology evolution. In particular, their transformation from relative technological weakness to their strengthening after adopting The Patents Act, 1970 followed by liberalisation and globalisation form the 1990s. This paper argues that these transformations have not only been the result of national policy, but also the competencies and capabilities of firms evolved over time. That is, there has been a co-evolution of public policy and firm strategy, each key and with changing impact on innovative capabilities in the pharmaceutical industry. The co-evolution of policy and technology (innovation) examined in this paper brings evidence to show how changes in public policy regimes have influenced the technological choices and trajectories of Indian pharmaceutical firms over time which in turn have facilitated the growth and evolution of this industry in India.

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Table of Contents

1. Introduction and Context 4

2. Indian Pharmaceutical Industry-Historical Context 5

3. The Evolving Policy Regime 6
- 3.1 Pre-Independence
- 3.2 Post-Independence (early years)
- 3.3 Developing the Patents Act, 1970
- 3.4 The Post-1970 Legal Regime
- 3.5 Post-Liberalisation

4. Policy Interventions and Technology Development 15
- 4.1 Post Independence Technology Efforts (early years)
- 4.2 Post-1970 Technology Progress
- 4.3 Technology Progress in the Liberalised Economy

5. Policy Impact on R&D Evolution 19
- 5.1 Government Initiatives Post Independence (early years)
- 5.2 R&D in the Post-1970 Regime
- 5.3 Post-Liberalization Research Initiatives by the Private Sector

6. Progress So Far 23

7. The New Patent Regime (TRIPs) and Challenges Ahead 25

8. Conclusion 26

9. References 28

Policy and Technology Co-evolution in the Indian Pharmaceutical Industry

1 Introduction and Context

The pharmaceutical industry is one of the most successful industries that India has built up since independence. The industry has performed exceedingly well in terms of production, domestic R&D, value addition, regional spread and diversification and most important of all, in providing affordable medicines for the masses. The literature suggests that the technological growth and development of a country are greatly influenced by the policies that help generate, absorb, diffuse and utilize technologies (Desai, 1980, Fikkert, 1993, Kumar and Squib, 1996). Policies to develop technology infrastructure can build the capacities and capabilities required to absorb and assimilate technological innovations from elsewhere or innovate upon it. The rapid technological growth and industrial development in the East Asian economies viz, Korea, Japan, Singapore, Hong Kong, Thailand, Malaysia, Indonesia and China has been widely acknowledged in the literature (Amsden, 1989, Lee, 2000). There seems to be a general consensus that the success of these economies owes a lot, in general, to their ability to imitate, absorb, assimilate and replicate foreign innovations facilitated by national level technology and industrial policies. In India too the government has been encouraging research, development and investment in pharmaceutical industry by making use of various policy tools. This paper examines the role of policy interventions in promoting local 'technology-generating efforts' and 'production enterprises' in the Indian pharmaceutical sector.

Ever since India gained its independence in 1947, science and technology in general, and health care and pharmaceutical industry in particular, have received considerable attention. The Indian government has taken many initiatives to encourage public, private as well as foreign investments in pharmaceutical R&D with an ultimate aim to make drugs available to the masses at affordable prices. The most significant initiative, however, was the non-recognition of pharmaceutical product patents in the 1970s. In the 1970s, India introduced complex laws and policies to regulate the domestic pharmaceutical industry particularly, to counteract monopoly abuses by foreign multinationals, and to jumpstart the local production.

Firms responded to various policy changes such as price controls, industrial licensing, foreign exchange regulations and the 1970s Patents Act in different and complex ways. From an open market dominated by foreign multinationals at the time of independence, the 1970s Patents Act propelled Indian firms on reverse engineering path and spurred the growth of highly inward looking pharmaceutical firms and industry focusing on the domestic market. The 'imitative' follower trajectory differs greatly from the technological trajectories followed by the firms in the US and Europe. Later liberalisation and globalisation forced the firms to look

beyond the domestic market and accordingly amend their research focus and market strategies. The transition has been quite complex and distinct in nature.

Given this context, this paper considers the causes and effects of the legal and policy changes in the evolution of the Indian pharmaceutical industry across its various stages of development. The paper examines: (i) the inception and growth (evolution) of Indian pharmaceutical industry before and in the early years after independence; (ii) the key elements of the integrated drug policy framework as it evolved between 1960s and 1990s; and (iii) its effectiveness in promoting technological advancements and capabilities. The paper analyses the key aspects of the drug development process followed by companies in the pre-reform period and overall growth of the industry. Documenting the events and evidences related to growth and technological development in the pre-TRIPs era this paper argues that policy has had complex and differing results over time and it plays a key role in shaping the technological trajectories of firms and in the overall growth of the pharmaceutical industry in India.

2 Indian Pharmaceutical Industry-Historical Context

Before Independence, India was fully dependent on other nations for vital drug supplies. The national pharmaceutical industry was in its infancy then and was dominated by foreign–held patents. Foreign held patents continued to rule the Indian pharmaceutical industry well after the independence and drug prices in India were among the highest in the world in the 1960s (Kefauver Senate Committee Report, 1962). The situation today is just the opposite. One of the important successes of economic and social development has been to make life saving drugs available at affordable prices. This success is largely attributed to a combination of policy-led technological advances consciously followed since late 1960s with the specific objective of providing affordable drugs for the masses.

It was The Indian Patents Act, 1970, that laid the foundation of this development. The policy tools, strategic interventions and technology efforts made after 1970 included incentives for: development of indigenous pharmaceutical industry; localization of production directly from bulk drugs and intermediates; emphasising generics over branded products; and price regulation through the Drug Prices Control Order (DPCO). The objective of building a national pharmaceutical innovation system was achieved through incentives for R&D activity to public and private enterprises coupled with an intellectual property protection framework designed to facilitate process innovation (of known compounds) capability in the country. The policy reforms came at a time when global pharmaceutical was at its peak and was redefining the economics of the domestic and global pharmaceutical industry making it extremely difficult for small entrepreneurs to participate in this economic and industrial revolution. These reforms not only enabled the emergence of a competitive domestic industry, as we shall see later in this paper, but also set the foundation for generic drug production.

Over the past decade, however, there have been a number of changes in the policy framework. Besides import liberalization and removal of restriction on foreign firms, DPCO has been diluted as a part of economic reforms. The Indian Patent Act of 1970 that governed the IPR regime over the past 30 years is undergoing important changes. Due to India's obligation under the TRIPs Agreement of WTO, which covers adoption of product patents by 2005 and provision of pipeline protection through exclusive marketing rights (EMRs), the IPR framework is in a transitory phase. India signed the TRIPs agreement in 1994 and joined the Paris Convention and the Patent Corporation Treaty in 1999. India had a ten years transition period to provide product patents. That is, until the end of 2004. The following section maps the evolution of policy framework relevant to the drugs and pharmaceutical industry.

3 The Evolving Policy Regime

Different policies adopted by the Indian government in pre-independence and post-independence era protected the nascent pharmaceutical industry and encouraged its gradual but strong evolution in the early years. The policy changes of the recent past may affect the growth itself or the pace of growth. Figure 1 clusters the developments under four major policy time frames that is: pre and post independence; post Patents Act 1970; post liberalization; and pre and post TRIPs. The subsequent sections analyse the co-evolution of policy and technology under different time frames and impact of recent policy changes on research and development.

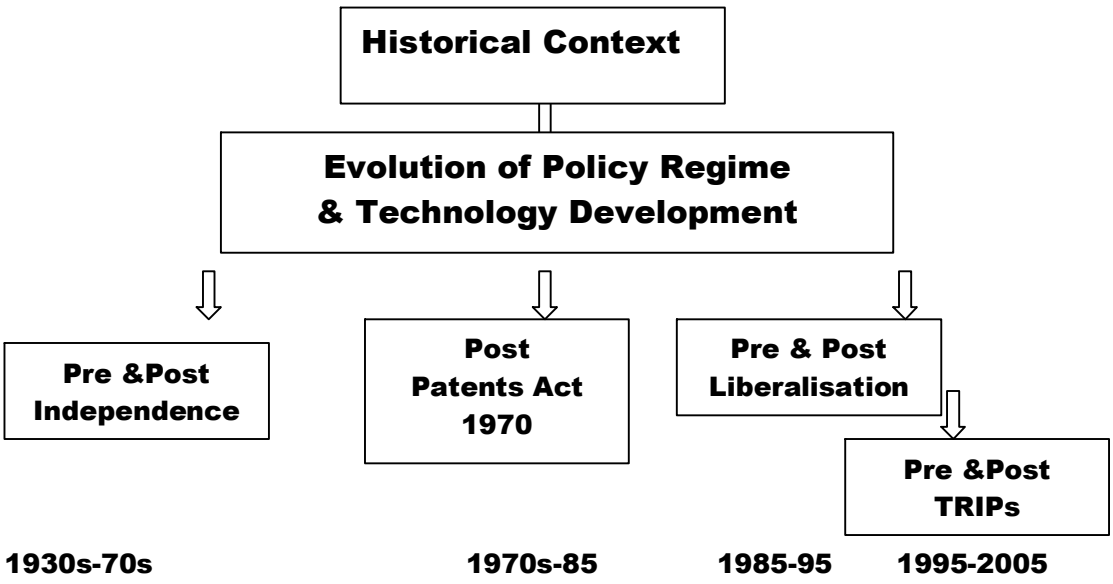

Figure 1: Integrated Policy Package Evolved Over 1930s to 2000

3.1 Pre-Independence

Allopathic medicines were introduced in India during the British Raj. The Government of British India set up medical schools and also initiated the production of modern drugs. Scientists undertook research in tropical diseases like Malaria, Typhoid and Cholera.

However, there was no local industry that produced allopathic drugs until the start of the 20th century.

Indigenous production of allopathic medicines started in 1901 primarily due to the pioneering efforts of Acharya P C Ray, an eminent Indian scientist. Dr. Ray set up a production unit called Bengal Chemicals and Pharmaceuticals Works in 1892 (incorporated in 1901). The unit began with the production of simple galenicals (medical preparations that are made from plants or animal tissues, rather than being created synthetically). It was followed by the establishment of Alembic Chemical Works in 1907 and Bengal Immunity in 1919. Four research institutes, namely the Haffkine Institute in Bombay, Central Research Institute in Kasauli, Kings Institute in Madras, and Pasteur Institute in Coonoor were also established between 1904 to 1907 to work upon sera and vaccines. The establishment of these research institutes and some private units initiated domestic drug production in India. A significant development of this period was the use of chemicals for treating various diseases and drugs like aspirin and barbiturates became available.

Dislocation of imports and steep rise in demand during the War provided further impetus to the indigenous firms and many more joined the bandwagon. Some of the bigger units set up during this period included Unichem, Chem Pharma, Indo Pharma, Indian Process Chemical Laboratory and Biochemical and Synthetic Products. Besides the production of quinine salts, new items like urea-stibamine were developed by local R&D.

With the resumption of imports after the War, local industry received a setback as it could not compete with imported products but it maintained steady growth. It took up the production of biological products like sera and vaccines, and anaesthetics. In 1930, Bengal Chemicals and Pharmaceuticals Works started the production of tetanus antitoxins. Nevertheless, indigenous production was able to meet only 13 percent (approx) of demand in 1939 and a large part of the domestic demand for drugs was met by imports.

The Second World War provided an opportunity for further expansion of local production[1]. With local demand for allopathic medicines increasing steeply and imports being completely cut off, several indigenous firms came into the market. At the start of the Second World War, drugs were being manufactured notably by Zandu Pharmaceutical Works, Calcutta Chemicals, Standard Pharmaceuticals, Chemical Industrial and Pharmaceutical Laboratories (Cipla) and East India Pharmaceutical Works. By the year 1941, the industry initiated production of chemotherapeutic drugs like arsenicals, anti-leprotic drugs, anti-dysentery drugs, alkaloids and colloidal preparation of calcium, silver, manganese and iodine. Thus, drugs based on indigenous raw materials as well as several synthetic drugs and biologicals

[1] During the thirties and early forties, a number of Indian companies started the local manufacture of formulations from imported bulk drugs and raw materials. For details on role of imported technology see Indian Pharmaceutical Industry-Problems and prospects, a study report published by NCAER, New Delhi (NCAER, 1984).

were manufactured during the war period. Technological progress made during the pre independence era is summarized in Table 1.

Table 1: Development of Manufacturing Know-how by Units

Time Frame	Firms/Institution	Product-line	Production levels
1900-1905	Haffkine Institute, Mumbai; Central Research Institute, Kasauli; Kings Institute, Madras; Pasteur Institute, Coonoor. Bengal Chemicals and Pharmaceuticals.	Research on Malaria, Typhoid, Cholera, Sera and Vaccines Simple galenicals	Nil
1905-1920	Alembic Chemical Works and Bengal Immunity	Chemicals like aspirin, barbiturates	NA
World War I	Unichem, Chem-Pharma, Indo-Pharma, Indian Process Chemical Laboratory, Biochemical and Synthetic Products	Quinine salts, urea-stibamine, other bio chemicals and synthetic products	NA
1930s-40s	Zandu Pharmaceuticals, Calcutta Chemicals, CIPLA, Standard Pharmaceuticals, East India Pharmaceuticals	Sera, Vaccines, Anesthetics, Antitoxins (Tetanus), anti-dysentery, anti-leprotic alkaloids, Chemotherapeutic drugs like arsenicals, Colloidal preparation of calcium, silver, manganese and iodine.	13 percent of the demand in 1939

Source: compiled by the author from various sources.

Although, in aggregate volume terms, the progress achieved in the production of fine chemicals and synthetic drugs was insignificant, the local industry had began to produce a large number of drugs for domestic market. But the production activity primarily consisted of the processing (refining and bottling of imported materials) of imported bulk drugs.

On the international front, with the introduction of sulpha drugs in mid-1930s and penicillin in 1940s, the international drug industry went through what is usually referred to as a 'therapeutic revolution'. The success of sulpha drugs and penicillin lured the drug firms in developed countries into research for developing new drugs. Accompanied by several other discoveries and inventions the drug industry transformed into a highly research and development oriented and technology savvy industry. Production and marketing of drugs

found a new focus and began to be organized by the large multinational corporations (MNCs) on a worldwide basis and on an unprecedented scale.

These developments in the west placed the Indian Industry at a great disadvantage. The Indian companies had to stop the production of many items that were manufactured during the war. Thus, at the time of independence the small production base that existed in India could not make much progress. The estimated value of production of medicines in 1947 was Rs. 10 crores only.

3.2 Post-Independence (early years)

Immediately after Independence, the Indian government took up the task of achieving high rates of economic progress with special emphasis on speedy industrialization. However, the key elements to encourage industrialization viz: capital in terms of machinery and equipment, trained technical work force and industrial know-how to harness the full potential of available raw materials and manpower, were not there. The economic planners felt that without external participation, progress in this crucial task would be severely delayed. There was an urgent need for foreign capital and technological resources in those industries where domestic activity was limited or non-existent. In order to facilitate the inflow of industrial know-how and capital from overseas investors, the following assurance was especially incorporated in the 1948 Industrial Policy Statement:

“No discrimination would be made between foreign and Indian undertakings in the application of general industrial policy.”

Making clear the nature of foreign participation, the First Five-Year Plan stated that:

“from the point of view of industrial development, it would be best if foreign investments in the country take the form of equity capital”.

These government policies soon after independence, paved the entry of several multinational pharmaceutical companies to establish manufacturing facilities in India as either subsidiary companies or collaborations with Indian entrepreneurs. These companies developed a number of formulations suited to Indian conditions with the help of technological skills provided by their overseas partners. The policies thus framed after independence resulted in facilitating the establishment of MNCs in India and their presence became so strong that even after two decades of independence the national scene was totally dominated by foreign held patents.

These MNCs simply imported formulations. None of the MNCs that included Glaxo, Boots, Parke Davis and Burroughs Wellcome, produced bulk drugs in India. They were solely interested in formulation production and marketing in India. Despite recognizing this, and very much in contrast to its policies towards other sectors, the government actually did not

discourage MNCs from competing in India for there was no substitute for MNCs' technology. But, India clearly lacked the benefits of the dynamic spill over effects that normally accompany the introduction of new technology since most products were imported by MNCs in finished form or in almost finished bulk form.

To facilitate diffusion of industrial know-how and technology the government encouraged foreign owned companies to set up manufacturing facilities together with one or more basic drugs. For the domestic sector, the Industrial Policy Statement 1956, grouped the pharmaceutical industry in the Schedule 'B' where both state and private sector could operate. Aided by the pragmatic policies of the government, many Indian and foreign firms established manufacturing facilities for producing a large number of bulk drugs. The leading pharmaceutical companies from USA, UK, Germany and Switzerland came to India with their technology, personnel, management tools and other associated resources.

This spurred production of a wide range of drugs in India and the industry achieved spectacular growth during the years 1952-1962 (Table 2).

Table 2: Selected Growth Indicators from 1952-62 (in Rs. Crores)

Indicators	**1952**	**1962**	**Growth Rate (%)**
Investment (sales value)	24	56	8.8
Bulk Drugs	NA	15	-
Formulations	35	100	10.9

Source: NCAER, 1984.

Some of the major changes that took place during this time include setting up public enterprises namely: Hindustan Antibiotics Ltd. in 1954 and Indian Drugs and Pharmaceuticals Ltd (IDPL) in 1961. These two enterprises played an important role not only in starting domestic production of key bulk drugs but also in diffusing substantial spillovers in terms of technical know-how, technology transfer and technology innovation process/system itself and more importantly in generating entrepreneurs. One of the important observations of the field work undertaken for this study including interaction with industry experts, has been that founders of many successful enterprises worked with these organizations initially. This is further confirmed by a survey that founders of one third of the 200 domestic enterprises surveyed had initially worked at IDPL, including the founder of immensely successful Dr. Reddy's Laboratories (Felker et al, 1997).

The modest growth rates achieved jointly by the public and private initiatives though useful and timely, were not enough to take care of the country's healthcare needs. Thus

pharmaceutical industry policies for the 20 years after independence continued to emphasize national health, rather than indigenous production and allowed MNCs to exploit the Indian market. By 1970, the industry had a huge MNC presence, most of which maintained minimal physical operations in India (Smith, 2000). Thus MNCs had the benefit of operating in a free market with exclusive privileges for 16 years (under the Patents and Design Act, 1911) without having to contribute anything to the local industry. The combination of these provisions had a negative impact on the industry. The government recognized the need to bring in changes to the laws and align them with the national agenda and aspirations of being a technologically self-reliant, independent country.

3.3 Developing the Patents Act, 1970

India inherited The Patents and Designs Act, 1911 from the colonial periods. This act allowed pharmaceutical inventors to patent their products, gave them exclusive privileges for 16 years and also provided that importation of the product satisfied the 'working' requirement of a patent. MNCs were quick to take advantage of these provisions and consistently imported bulk drugs from their home countries. They also patented heavily in India. Between 1947 and 1957, 99 per cent of 1704 drugs and pharmaceuticals patents in India were held by foreign MNCs (Dubey, 1999). Between 1967 and 1970 applications for patents by foreign MNCs exceeded patent applications of Indians by over 340 per cent (Ratan, 2001).

A number of cases highlighted that foreign patent owners were neither using their patents for domestic manufacture of drugs nor allowing them to be used by local firms. For example, Beecham introduced semi-synthetic penicillin ampicillin in Europe in the early 1960s but was unwilling to market these drugs in India. The same situation existed with the cardiac drug propranolol introduced by ICI internationally in the mid 60's. Desai (1980) in a questionnaire survey of 53 firms conducted in 1969 found that by and large foreign firms were against any liberalization of patent laws. Indian firms were not against patents but wanted greater access to patented know-how especially when patent owners were not allowing their patents to be used. The conflict of views was stronger in chemicals and pharmaceuticals where patents had been used as a policy tool to prevent entry of Indian firms. A few domestic chemical and pharmaceutical firms that tried to develop their own technologies in 1960s ran into trouble with foreign patent owners (Desai, 1980).

The impact of 'product patenting' was evident on the pharmaceutical industry. The local manufacturing was not widespread and the drug prices in India were among the highest in the world. Such pressures in the late 1960s necessitated the promulgation of the Patents Act, 1970.

The 1970 Patents Act, which came into effect in 1972, reduced the scope of patentability in food, chemicals and pharmaceuticals only to processes and not products. Since virtually any chemical compound can be made by a variety of processes, the scope of patents was greatly

reduced. In addition, the term of process patents was reduced to 7 years from the date of patent grant or 5 years from the date of sealing whichever was shorter in food, drugs and chemicals, and to 14 years for other products. The provision of compulsory licensing was also introduced and compulsory licenses could be issued after a three-year grace period from the sealing of the patent. Importation of the patented subject matter no longer satisfied the working requirement of a patent.

The Controller of Patents could grant compulsory licenses when the patent was not available to the public of India at a reasonable price. The controller had the power to determine the terms and conditions of the license agreement and to control royalty payments. The government also took an interventionist approach in determining the terms and conditions of licensing agreements that involved technology transfer. This left a lot of discretion in the hands of the government. As a result several life saving drugs and other drugs earlier unavailable, like propranolol and ampicillin, were introduced in India by the national sector immediately after the Act came into being. As a consequence of Patents Act 1970, in the absence of monopolies, even the MNCs were compelled to sell their products at competitive prices.

Whilst proceeding to evaluate the objectives and ultimate effects of the Patents Act 1970 on indigenous technology and capability development in India, it is worthwhile to chronologically outline the important policy reforms that took place after the Patents Act 1970 was adopted. The following section traces the post-1970 policy developments.

3.4 The Post-1970 Legal Regime

A complex web of laws, regulations and policies, aiming for an integrated approach to industrial revolution was set up following the Patents Act 1970. Establishment of national health, education and innovation systems all played an equally important role in the industrial evolution. Industrial trade, policy and technology policy frameworks evolved rapidly during this period. These policies can be broadly classified into two categories viz, industrial policy and pricing policy. The subsequent text provides the gist of inception, implementation and implications of various industrial and pricing policies adopted by the government to promote drugs and pharmaceutical industry in India.

Drug Policy

In 1974, the government appointed the famous Hathi Committee named after its chairman Mr. Jaisukhlal Hathi mainly to look into the progress made by the Indian pharmaceutical industry after adopting the Patents Act, 1970. After extensive investigation into the problems and prospects of achieving greater extent of self-reliance the committee made a number of recommendations in its report in 1975. Parliament, based on the recommendations of Hathi Committee formed a New Drug Policy (NDP) that was announced in March 1978. The NDP

had three stated objectives: availability of quality drugs at reasonable prices; self-reliance in drug technology; and self-sufficiency in drugs production.

The policy involved elaborate use of industrial licensing system. Indian producers were given incentives through relaxation of licensing provisions. They were allowed to produce formulations and bulk drugs in the ratio of 10:1 in a regime that laid emphasis on the production of bulk drugs. Foreign firms, however, were not given such relaxations to ensure they increased production of bulk drugs in India. In fact, foreign firms producing formulations based on imported bulk drugs and intermediates had to start manufacturing from the basic stages within 2 years.

Along the same lines, the policy attempted to promote the development of local R&D facilities, while ensuring technology imports, wherever necessary. Whilst, public firms and national laboratories were promoted in an attempt to strengthen design and engineering component, new obligations were imposed on foreign firms. Foreign firms with an annual turnover of more than Rs. 50 million were obliged to have local R&D facilities with a capital investment of at least 20 percent of their net block. These firms were also required to spend at least 4 per cent of their sales turnover as recurring expenditure on R&D facilities.

As the industry evolved, the need was felt for a new line of action. The drug policy was revised in 1986 with an enhanced focus on quality and drug access. However, the basic objective of indigenous capacity building in technology, infrastructure and knowledge remained intact. The main objectives of the Drug Policy, 1986, titled as 'Measures for Rationalisation, Quality Control and Growth of Drugs & Pharmaceuticals industry in India' was to ensure abundant availability of essential and life saving medicines of good quality at reasonable prices.

Pricing Policy

Price Control has been an important feature of the Indian pharmaceutical industry. Government control on drug sale prices began in 1962 with Drugs (Display of Prices) Order, 1962. It evolved further with Drugs (Control of Prices) Order, 1963 and Drugs (Display and Control) Order, 1966, when it became obligatory for the manufacturers to publish their prices and for traders to display them. The first Drug Prices Control Order (DPCO) was issued in 1970 with three main objectives: controlled bulk drug prices; controlled prices of selected formulations; and a ceiling on overall profit.

The order had the prime objective of protecting consumer welfare by reducing the prices of essential drugs on the one hand and ensuring reasonable profits to producers on the other. The 18 essential bulk drugs brought under the purview of DPCO 1970, accounted for less than 9 per cent of the total value of drugs marketed.

Later the Hathi Committee in 1975 highlighted various anomalies and distortions in the cost and price structure of the industry. The committee mentioned these distortions as the product of a rigid price control system applied to a large number of products extending over a long period of time. Based on these findings and following the promulgation of the NDP 1978, the DPCO 1970 was revised in 1979.

Under the revised DPCO, 1979, all drugs were divided into four categories: (i) Life Saving; (ii) Essential; (iii) Less-Essential; and (iv) Non-Essential. Of these, the first three came under the ambit of price controls with mark up (profits) allowed of 40 per cent, 55 per cent and 100 per cent respectively. In all, 347 drugs came under the purview of DPCO accounting for 90 per cent of the industry. The underlying objective was to make it difficult for the MNCs to make large profits thus making life-saving and essential drugs easily affordable. For stimulating indigenous production and ensuring availability of essential drugs the small scale sector was kept out of price control and new bulk drugs developed through local R&D in India were also exempted for a period of five years (NCEAR, 1984, Chaudhuri, 2004).

As was expected, the price control of essential drugs resulted in shifts in production patterns. Owing to tighter price control in the first two categories, the MNCs shifted their focus to less essential and non-essential formulations. This had somewhat negative impact on the availability of essential drugs. Table 3 shows shifts in the drug production patterns in response to various price controls. This new attempt and concept (DPCO, 1979) to control prices by the government met with major resistance by the industry which led the government to issue a modified DPCO in 1987 that reduced the scope of DPCO to 166 drugs (from 347) and enhanced the stipulated mark-up for the included formulations. The scope of price controls was further restricted in the 1990s as a part of the reforms (Watal, 2000) which is discussed later in the paper.

Table 3: Drug Production in Response to Price Policy (in percentages)

DPCO Category	1978	1979	1980
I Life saving	4.5	4.2	3.6
II Essential	16.7	14.8	13.2
III Marginal (Less-essential)	67.1	67.0	68.6
IV Decontrolled (Non-essential)	11.7	13.2	14.6

Source: T.L Narayana, 1982

3.5 Post-Liberalisation

As an integral part of economic reforms, the industrial, trade and technology policy framework that had evolved from 1950s to late 1980s was considerably changed in the 1990s. The New Industrial Policy (NIP) announced on 24th July 1991 and subsequent amendments brought far reaching changes in the policy regime evolved thus far. The liberalisation of the economy in

1991 had a major impact on the two vital policies (Drug Policy and Price Controls) related to the pharmaceutical industry which are discussed below.

Drug Policy

In September 1994, government announced a revision of the Drug Policy, 1986 making major modifications. The modifications included: abolishing licensing policy for all bulk drugs except those reserved exclusively for the public sector units and other using new technologies; removing limitations on the use of imported bulk drugs; allowing foreign holdings up to 51 per cent; and automatic approval for foreign technology agreements in the case of almost all drugs. Later on, the pharmaceutical industry was included in the list for automatic approval up to 74 per cent in March 2000 and to 100 per cent in December 2001.

Price Controls

Another aspect of the reforms has been substantial dilution of the price controls. The Drug Policy, 1994 liberalized the criteria for selecting drugs for price controls. Inline with the changes in drug policy a new DPCO was notified in January 1995 bringing down the number of drugs under the ambit of price controls to 74 from 166 (as was under DPCO, 1987). These 74 drugs accounted for only about 40 percent of the total market thus setting the bulk of the pharmaceuticals market out of price controls. The exemption period for new drugs, produced through indigenous R&D was also increased from 5 years to 10 years. Although, the piecemeal reforms have been criticized for slow industrial progress gradual liberalization of the policy regime - from overbearing governmental control to subtle emergence of 'open market' principles gave time and opportunity to firms and the local administration to adapt to the changing scenarios.

So far this paper has discussed the evolution of policy regime through the 1900s to 2000 and analyzed, specifically, policies relevant for R&D, technology and overall growth of the pharmaceutical industry in India. The following sections trace the technological progress made in response to these policy changes during the corresponding time frames.

4 Policy Interventions and Technology Development

Overall, the case of the Indian pharmaceutical industry provides a highly instructive example of the complexity of building technical capability. The setting up of the public sector plants under HAL and IDPL to produce antibiotics and synthetic drugs was a major government initiative in the technological development of Indian pharmaceutical industry. These were set up at a time when MNCs were neither supportive of setting up basic manufacturing facilities themselves, nor willing to provide technology to local firms. The non-recognition of product patents, compulsory licensing and licenses of rights all ensured that the MNCs could not use patents to prevent technology transfer and diffusion to the local innovation system. The combined impact of policy initiatives facilitated the diffusion of technology form MNCs to local

firms and also within the local firms. A chronological review of the policy events and their impact on technology development in the following paragraphs provides a better picture.

4.1 Post Independence Technology Efforts (early years)

The modest technology efforts made by Indian scientists and firms before independence have already been discussed in the previous section. At the time when India gained her independence in 1947, the pharmaceutical industry had a very weak domestic technological base for local production. After independence, although the attitude of economic planners and policy makers was more inclined towards foreign capital for achieving the desired tempo of industrialization, the pharmaceutical industry belonged to a different class. The Industrial Policy Statement of 1948 placed it under the category of 'basic industries' requiring considerable investment and a high degree of technical skills. The growth of the pharmaceutical industry was subjected to planned targets and monitoring.

Unlike many other industries the global pharmaceutical industry had become highly research-intensive by the end of 1950s. A large number of therapeutic drugs were being invented and introduced in the market which could be protected through patents and brand names. The emphasis had shifted from treating the symptoms to treating the disease itself. New therapeutic developments in the west replaced many older drugs by newer drugs like sulpha, antibiotics, vitamins, hormones, antihistamines, tranquilizers and psycho pharmacological substances. These developments in therapy changed the profile of the pharmaceutical companies. In order to attain higher scale of economies in production, marketing and distribution and to match pace with a high rate of discovery and introduction of new drugs in the market, pharmaceutical companies all over the world grew in size.

The Indian pharmaceutical industry, still in its infancy, could not match the developmental pace and in fact had to stop production of many drugs that it had previously manufactured. Recognizing the international character of the pharmaceutical industry, the government permitted entry of MNCs to set up in India. Although this was not entirely in favour of the domestic industry, it provided much needed technological and financial support for a strong domestic production base (Desai, 1989). It provided much needed access to information and technical know-how related to the new discoveries in the west. In addition, Indian companies could absorb the modern managerial practices from MNCs to establish modern production facilities.

Though the industry showed steady progress, it was mainly processing and formulating medicines based on imported fine chemicals and bulk drugs. In 1952, only a few drugs like tetanus anti toxin, PAS and quinoline were produced from basic stages. Indigenous production of new drugs like antibiotics, anti-diabetics and vitamins had not commenced. Although FDI was welcomed and given national treatment, MNCs were reluctant to setup manufacturing facilities for these products in India.

In view of these imbalances, the Pharmaceutical Enquiry Committee set up by the government in 1954 (The Ayyangar Committee), recommended immediate rectification of various aspects such as licensing, foreign collaborations, production, selling and distribution of bulk drugs. The committee laid down the guiding principles for future collaboration, emphasizing that foreign collaborations should be allowed only when a firm agrees to undertake the manufacture of at least a few basic drugs from the primary raw materials. In order to facilitate a free inflow of industrial know how and knowledge the government allowed foreign-owned companies to set up facilities to manufacture a variety of formulations together with one or more basic drugs in India with or without an Indian partner. These foreign collaborations encouraged by the government helped in achieving rapid industrialization.

It is well accepted that the policies and programs formulated based on the Ayyangar Committee recommendations laid the true foundation for the Industry's dynamic growth witnessed during later years. The process technology in use encompassed fermentation, chemical synthesis and isolation from plant or animal materials. Basic research also got a boost through the establishment of comprehensive research centres established by Ciba Geigy, Hoechst and Sarabhai. Several new companies were allowed to be started with majority capital participation. This facilitated the expansion of domestic sector and many private units came up during this period. For example, Cadila in 1951, Ranbaxy in 1961, Lupin in 1971, Torrent in 1972, Sun in 1983, Nicholas Piramal in 1988 and many more.

Private enterprises were supplemented by the establishment and promotion of the public sector. To reduce the dependence on imports and on MNCs, at least for vitally needed antibiotics, the government made large investments in establishing a network of public sector enterprises (Ramani, 2002). Two large public sector companies namely HAL and IDPL were set up by the government. HAL with WHO-UNICEF assistance for the production of penicillin and IDPL with Soviet technical know-how and financial assistance for the production of antibiotics, synthetic drugs and surgical instruments. IDPL served as a vehicle for a comprehensive Soviet-sponsored programme, in which Russians supplied machinery, personnel and know-how to produce antibiotics.

Thus a large mass of technology modern as well as not so modern was imported into India from 1950-1970. HAL and IDPL played an important historical role in establishing a technology base in India. They not only showed that it was possible to produce drugs in India at competitive costs but also helped develop human and physical capital, some of which slowly spilled over to other companies.

4.2 Post-1970 Technology Progress

Before 1970, patent protection served to encourage foreign inventors and foreign R&D. MNCs patented their inventions in India, but did not produce locally, using the patents to establish protected foreign market in the country (Ayyangar Report, 1959, p12). This not only denied

the spill overs of technologies developed by MNCs to the local innovation system, but it also did not help developing local technological capabilities.

The need for a system that encouraged technology acquisition, transfer, development, diffusion and incremental innovation was obvious. Patent Law was used as a tool to establish this system in India. The Patents Act, 1970, represented a significant change in the legal and technological regime and had an enormous impact on the technological evolution of pharmaceutical industry in India. Beginning in the late 1970s and early 1980s, legal reverse engineering made new technologies and new drugs available easily and at an affordable price.

India had developed production-scale chemical synthesis capabilities in the 1950s. The chemical structure of a patented drug, and often its chemical synthesis, either could be found in the patent application or published pharmaceutical literature. Moreover, reverse engineering, subsequent development and production of patented drugs required only a fraction of time and money as compared to that involved in the original drug discovery process. Guided by these principles both the private Indian firms and public laboratories focused their R&D efforts on imitative process R&D. Thus technology progress during this period was mainly driven by 'technology-followers' approach and 'low-cost innovations and products' goal.

Some private firms such as, Ranbaxy, Lupin, Torrent and Sun took the first few steps towards technological maturity during the late 1980s. These firms with global ambitions grew less reliant on reverse engineering and started moving towards creating non-infringing processes. Based on their expertise and capabilities for process R&D, and driven by the large global generic markets of the developed world, these firms gradually created capability for generics R&D by improving in process research. Through the late 1980s, Indian firms grew increasingly sophisticated in their management and their strategy, focusing on backward integration, fragmentation and enhancing plant capacities.

Thus, policy measures during the 1970s and 1980s such as protected economy, restricted technology imports and foreign investments, and non-recognition of product patents helped local industry to initiate production of existing drugs at a smaller scale. The policy environment provided an opportunity to learn while doing by eliminating fear of competition from more established and technologically advanced MNCs. Opportunities for learning-by-doing were available (Felker, 1997). Gradual expansion without market pressures provided time to Indian firms for enhancing their technical expertise, infrastructure, range of drugs, production capacities and market reach within the country.

4.3 Technology Progress in the Liberalised Economy

Before liberalization began, protection of domestic production and local technological efforts enabled India to build up a diverse and fairly sophisticated base in the pharmaceutical sector. However, technological backwardness and lack of genuinely innovative products was evident (Lall, 1987). The fresh lease of reforms (liberalization) provided much needed pace for technological advancement. Once the Indian market was opened up to foreign firms and import of goods, demand for improved manufacturing processes and new products had driven the need for new technology and innovative products at par with international products.

Much new technology was imported but some leading firms started investing more in in-house R&D as a move to build a proprietary technological base. Some firms increasingly started focusing on novel drug delivery systems (NDDS) thereby adding their own value to the existing products. “There were even more successful attempts to produce products better tailored than MNC drugs for the Indian market” (Smith, 2000, p14).

The Indian pharmaceutical firms responded to liberalization in many different ways. Firms like Cipla, Alembic, Cadila, Zydus and Lupin improved their manufacturing efficiency and established large production facilities. Some firms like Sun, Torrent, Dabur, Cadila, Ranbaxy and Wockhardt restructured and shifted their technology focus, product basket and market focus. Special emphasis was given to marketing and distribution networks by almost all leading pharmaceutical firms during this period. Domestic leaders substantially increased their in-house R&D investments and implemented new approaches to drug/product development.

Some ambitious and visionary firms such as Ranbaxy, Dr. Reddy’s and Cipla had started taking technological initiatives even before liberalization. Nonetheless, liberalization did set the pace. Thus, competition with foreign firms and foreign products in the domestic market, exposure to the global markets, and realisation of future regulatory changes provided much needed innovative orientation to the imitative research in the early 1990s.

5 Policy Impact on R&D Evolution

The earliest pharmaceutical research and manufacturing activities in India were started by three private companies (Bengal Immunity, Bengal Chemicals and Alembic) and four government research institutes (Haffkine, Pasteur, King and Kasauli) in the early 1900s. The R&D progress made during pre-independence era has been covered earlier in this paper. The research and development efforts made afterwards are covered now.

5.1 Government Initiatives Post Independence (early years)

Since the 1950s, the Indian government has funded and conducted over 80 per cent of formal R&D. Government R&D has been largely conducted in autonomous central government research laboratories. The government invested in industrial research through Ministerial departments especially through the Council for Scientific and Industrial Research (CSIR).

CSIR, consisting of 43 industrial R&D laboratories was established solely to provide a research base for Indian industry. For a long period, support systems and finances were made available only to the public sector which could not meet expectations. Little consideration was given to the private sector. But the results have been quite unimpressive (NCEAR, 1984). Four successive parliamentary committee reports on CSIR submitted between 1954-1986 each concluded that CSIR has made a negligible contribution to Indian industry. Government R&D thus played a negligible role as a source of technology.

In order to identify and fill the technology gaps, the government appointed various committees from time to time and made several policy amendments to encourage research in the domestic industry. R&D in Indian pharmaceutical industry was encouraged by the government with the aid of policy tools initially through the public sector which later on was picked up by the private sector.

Public Sector Contribution

Although public sector undertakings were bedevilled by technological obsolescence (purchase of obsolete technologies), business inexperience, management control and technology transfer (absorption) related problems, the public companies like HAL and IDPL created a new climate after independence and generated much needed confidence that India was also capable of manufacturing bulk drugs.

HAL started penicillin production with the technical assistance of WHO and UNICEF in 1954. However, indigenous R&D efforts to improve upon the acquired technology could not match international standards. HAL also imported technologies from Merck of USA and Glaxo for the production of streptomycin in 1962. The technologies imported from other countries could not always be implemented and required considerable modifications and local adaptations. Indian expertise, scientific knowledge and technical skills played an important role in the implementation and absorption of acquired technologies. Although HAL did not succeed as expected, it provided technological leads, trained manpower and expertise in commercial production of antibiotics.

Establishment of IDPL in 1961 by the government mainly for the manufacture of bulk drugs, is regarded as a great initiative in the history of the Indian pharmaceutical industry. There were hardly any major Indian pharmaceutical companies existing at that time in India. IDPL became a role model to many enterprises and provided a tremendous boost to indigenous efforts. After a period of learning and adaptation and with protection from the government, drugs were massively produced, although without much quality control or research. In latter times, spin-offs of HAL, IDPL and other state owned companies that went to private hands reached high quality standards and established modern managing practices. Some of the CSIR laboratories, notably, Central Drug Research Institute (CDRI) and Regional Research Laboratory (RRL) Hyderabad also developed some new drugs (Table 4).

Table 4: New Drugs Developed in India

Drug	Year	Use	Institution
Urea Stibamine	1921	Kala-azar	School of Tropical Medicine, Calcutta
Methaqualone	1956	Non-barbiturate hypnotic	RRL, Hyderabad, Lucknow University
Hamycin	1961	Anti-fungal	HAL, Pune
Centimizone	1972	Anti-thyroid	CDRI, Lucknow
Sintamil	1978	Anti-depressant	Ciba Giegy, Mumbai
Tinazolin	1978	Nasal decongestant	Ciba Giegy, Mumbai
Tromaril	1980	Anti-inflammatory	RRL, Hydearbad
Isaptent	1985	Cervical dilator	CDRI, Lucknow
Guglipid	1986	Hypolipidaemic	CDRI, Lucknow
Centbucridine	1987	Local anesthetic	CDRI, Lucknow
Centbutindole	1987	Neuroleptic	CDRI, Lucknow
Centchroman	1991	Nonsteroidal Oral Contraceptive	CDRI, Lucknow
Chandonium Iodide	1994	Neurmuscular blocking agent	CDRI, Lucknow, Punjab University
Centpropazine	1996	Anti-depressant	CDRI, Lucknow
Arteether	1997	Anti-Malarial	CDRI, Lucknow, CIMAP, Lucknow
Standardised Brahmi extract	1997	Herbal remedy for memory improvement	CDRI, Lucknow

Source: The Structure of Indian Industry, Oxford University Press, 2004.

5.2 R&D in the Post-1970 Regime

In 1970, India did not yet have the basic necessary resources (know-hows, skills) to conduct R&D in the domestic industry. The patent system was recognized as a useful instrument to

encourage knowledge, information and technology diffusion for industrial R&D. In addition, the government encouraged industrial enterprises to take up in-house R&D through various policy instruments. In 1974 a scheme for recognition of in-house R&D establishments of industrial units was started. The recognised R&D units received facilities for importing equipment, raw materials, samples and prototypes for their R&D work under Open General License, without any ceiling. In few cases, foreign collaborations approvals were granted with the understanding that importer would undertake R&D activity to absorb the technology. The NDP, 1978 also obliged foreign companies with turnover in excess of Rs. 50 million to have R&D facilities within India to facilitate research in India.

The Technology Absorption and Adaptation Scheme (TAAS) was initiated under the aegis of Department of Scientific and Industrial Research (DSIR) to assist absorption and adaptation of imported technologies. To promote a 'research tradition' in Indian industry, the DSIR also launched a scheme to grant recognition to Scientific and Industrial Research Organisations (SIROs). SIROs were fully exempted from any custom and excise duty on the imports of equipment, instruments, accessories and consumables related to R&D activities (DSIR, 1990). The policy also specified one to two per cent higher profit ceiling for companies engaged in approved R&D work.

In spite of all these incentives to encourage R&D, the outcome has not been very encouraging. Foreign firms have been cautious enough in carrying out any research and innovation in unprotected environments. Public sector firms with foreign affiliations have bought up to date technology but they have essentially been using one step or two step processes from late intermediates. The organized private sector (large firms) acquired technological capability through a variety of methods, including in-house R&D, interaction with national research laboratories and unreported and informal purchase of technology from abroad. Since there was no reward for innovation and no penalty for imitation, these firms also choose the path of reverse engineering assuring no risk and instant returns. Nevertheless, the private firms developed latest medicines launched in the international markets by MNCs using most cost effective processes. Contributions form the private sectors in the R&D evolution of Indian pharmaceutical industry are summarized below.

5.3 Post-Liberalization Research Initiatives by the Private Sector

Through the 1980s and early 1990s, private enterprises grew increasingly sophisticated in their management and their strategy, focusing on backward integration, fragmentation and increasing plant capacities. Research, innovation and quality were still no concern at all. Insignificant research and innovation, domestic price wars, and substandard quality of drugs in late 1980s made the policy makers realize the need to induce innovation and quality in drug development. Liberalization served as an important policy tool to initiate innovation based competition. The process however was hesitant, intermittent and patchy. It was only in 1992, that a serious attempt was made to free up trade, domestic competition and technology

inflows and attract foreign investment (Lall, 2001). The first few steps towards serious research and development were taken during this period.

Some local firms grew less reliant on reverse engineering and enhanced their focus on R&D and their own value additions to the products. The private firms gradually advanced to creative imitation stage that is the chiral synthesis and produced good quality generics. After liberalisation the top Indian firms enhanced their focus and R&D spend on NDDS and NCEs. Dr. Reddy's initiated research related to NCEs even before liberalization and became the first Indian firm to develop its own molecule. Similarly, Ranbaxy, India's largest home-grown pharmaceutical firm, like many other Indian firms benefited from the 1970 Patents Act and started by producing a series of reverse-engineered drugs but began investing more in R&D even before liberalization. The investments in R&D were further enhanced and focus on NDDR facilitated with the Intellectual property rights requirements of the Uruguay Round.

After 1995, a few innovative pharmaceutical firms have started moving up the value chain by concentrating on analogue research and new drug delivery systems. Some of the companies in this category are Cipla, Nicholas Piramal, Dabur, Torrent, Sun, Lupin, Wockhardt, Aurbindo, Zydus and Cadila. These firms have started focusing on developing intermediate capability (analogue research and NDDS) that could give leverage (for example, Exclusive Marketing Rights) to Indian firms in the market and create intellectual property.

Qualitatively, R&D in India is still at a very nascent stage. Until recently firms have remained more focused on the less research-intensive area of process development rather than NCEs. The emphasis has been on reverse engineering and production of generics. The knowledge and research base of the domestic firms is deeply rooted in organic and synthetic chemistry. Although there have been significant process innovations based on the knowledge created by others, innovations in the forms of new drugs based on indigenous R&D have been clearly absent.

6 Progress So Far

Over the years the Indian pharmaceutical industry has evolved with a much higher emphasis on technological development and R&D activity. Earlier, the government made considerable investments in autonomous R&D laboratories but the commercialization from these sources was much below expectations. Later, several firms established in-house R&D facilities, essentially focusing on indigenization. In the beginning, industry focused more on the process engineering and innovating around an existing product but gradually the industry has enhanced its focus and investment in research and development, and infrastructure development.

Technological development in India is reflected in the wide range of bulk drugs being produced from basic stages, through complex multi-stage synthesis and intricate fermentation

and extraction technology. Indigenous firms including both the older firms like Cipla, Alembic, Cadila, Ranbaxy,Torrent and newer ones like Dr. Reddy's, Lupin, Sun and Zydus have developed the expertise to manufacture bulk drugs through innovative and cost-effective processes. Currently, India is self sufficient in a large number of essential drugs. The indigenous sector has built tremendous strength in developing cost efficient processes to manufacture international quality drugs from basic stages and India is now a major force to reckon with in the western markets for a number of essential drugs.

Indian firms with their economical process innovations and timely policy support have emerged as competitive suppliers of a large number of generic drugs in the world. USA is the biggest market for India's pharmaceutical exports (mainly bulk drugs) accounting for 10-12.5 per cent of exports. "Something that would have been inconceivable three decades ago has happened- India is now a net exporter of drugs and has earned a considerable reputation in the international market as a dependable bulk drug manufacturer" (Adelman and Baldia, 1996, p525). Although R&D in India is still at a very nascent stage and is mainly focused on process development rather than new molecular searching, with the knowledge base of local companies firmly embedded in organic and synthetic chemistry, their capability to produce satisfactory substitutes for many patented western drugs is unquestionable (Ramani, 2002).

Important targets and numbers achieved by Indian pharmaceutical industry during its evolution in terms of investment, production, import and export are summarized in Table 5. Table 6 summarizes the increasing R&D expenditure from the 1980s to the 2000s.

Table 5: Growth Indicators in Rs. Crores

	1965-66	**2000-01**
Capital Investment	140	2,900
Production: Formulations	150	18,354
Production: Bulk Drugs	18	4,533
Imports	8.20	2,980
Exports	3.05	8,730
R&D Expenditure	3	370

Source: IDMA Bulletin, Various Issues. 1crore= 10,000,000=10 million

Table 6: R & D Expenditure in Pharmaceutical Industry

Year	(in Rs. Crores)
1980-81	14.75
1997-98	220
1998-99	260
1999-00	320

R & D Expenditure as % of sales	2.0%

Source: IDMA Bulletin, Various Issues.

Investment in pharmaceutical R&D has been rising steadily. From Rs.14.75 crores in 1980-81 the R&D expenditure has grown to Rs.260 crores in 1998-99 and to Rs.320 crores in 1999-2000. Direct investment in the drug industry increased from Rs.225 crores in 1973 to Rs.1100 crores in 1993 and it was estimated to be 2,900 crores in 2001. The present R&D spend accounting for 2 per cent of the pharmaceutical industry's turnover is estimated to rise to five per cent by 2005-06.

The statistics and other qualitative data presented in this paper has shown that legal reforms helped develop an indigenous industry, enhanced production levels, ensured self sufficiency, made inexpensive pharmaceuticals available, and inversed the export-import ratios. A progressive and well-timed policy framework, evolved thus far, has enabled Indian firms to be competitive in both formulations and bulk drugs production.

7 The New Patent Regime (TRIPs) and Challenges Ahead

Government policies have in many respects been salutary. The growth of the Indian pharmaceutical over the last four decades owes a lot to the 1970 Patent Act, which allowed the domestic marketing of patented products without a license. During the process patent regime, Indian firms developed competence in applied research for developing production-process technologies, particularly for synthetic bulk drugs. The production of drugs increased many folds between the early 1970s and the 1990s. India has achieved global recognition as a low cost producer and supplier of quality bulk drugs and formulations to the world. In 1999-2000, drugs and pharmaceutical exports were Rs. 6631 crores out of a total production of Rs. 19,737 crores (Ministry of Chemicals and Fertilisers, 2001).

However, the drugs and pharmaceutical industry in India today faces many challenges stemming from liberalization of the Indian economy, globalization of the world economy and challenges related to new obligations undertaken by India under TRIPs. A product patent regime under TRIPs obligation will challenge both the government and local firms in many ways. The TRIPs agreement requires WTO members to include ‘recognition of product patents for pharmaceuticals with 20 year terms’ in their domestic patent laws. Besides, importation of patented products once again satisfies the ‘working’ requirement of a patent and compulsory licensing can only be granted in exceptional circumstances such as national emergencies (Pharma Policy, 2002).

At the national level, these challenges require a change in emphasis in the current pharmaceutical policy and the need for new initiatives beyond those enumerated in the Drug policy 1985, and modified in 1994, so that policy inputs are directed more towards promoting accelerated growth of the pharmaceutical industry and towards making it more internationally

competitive. Similarly, changes are required at firm level with more emphasis and focus on technology and innovation. In the process patent regime the emphasis has been on reverse engineering and production of generics and the R&D focus of firms during this era clearly reflects this. Although, it has helped the industry to grow exponentially, the lack of effort to integrate other scientific disciplines restricts the opportunities to engineer innovations in the product patent regime.

The operationalisation of the new patent regime is likely to bring about fundamental changes in the composition of the pharmaceutical sector as has happened in the past. Although domestic R&D intensity has improved during the later part of the 1990s, the overall level of investment has remained very low (Pradhan, 2003). A shift to a product patent regime would demand capability development for indigenous research to enable the industry to achieve sustainable growth. R&D, in fact has been identified as the 'survival' kit by pharmaceutical experts. The large players have already started upgrading their R&D capabilities and various approaches are being adopted to cut time and cost factors and add quality and innovation in drug development. For example licensing product patents from patent holders; acquiring their own patents through indigenous R&D; and integrating new knowledge and resources from external sources. Events such as mergers, acquisitions, R&D collaborations, and internationalization have affected the pharmaceutical firms at all levels. Strategic outsourcing has assumed an increasingly important role in the operations of established as well as emerging pharmaceutical firms. The emergence of a "niche" service sector comprising Clinical Research Organizations, popularly known as CROs is noteworthy.

Global competition has facilitated diffusion of new technology and information and as a consequence, industry structure has evolved rapidly, thereby forcing firms to develop new strategies to enable them to compete effectively and survive. Although these activities are not uncommon, particularly as an industry matures, competition increases and a shift towards a global marketplace occurs. How the firms and the industry in India will evolve in the post-2005 era amidst highly regulated, competitive and knowledge-intensive environment, however, remains to be seen.

8 Conclusion

The data and evidence presented in this paper confirm that, ever since its inception, the pharmaceutical industry in India has been deeply affected by a variety of public policy, ranging from patent and price controls to drug policy and industrial policy. The periodisation from pre-independence to post-trips era has been immensely useful in encapsulating technological and capability development of the Indian pharmaceutical industry during different policy regimes.

At the time of independence, India was technologically backward, had an open market dominated by foreign multinationals, and had very high entry barriers for local enterprises.

Until 1970, the Indian pharmaceutical industry was suffering from exploitation of patent monopolies by MNCs. The legal and policy reforms relating to pharmaceuticals from 1970 onwards were both wide-ranging and effective.

India's policy change came at a time when a large number of blockbuster medicines were being introduced by the Western firms. Indian firms, however, were evolving new techniques that assisted reverse engineering at that time. Nevertheless, the imitation research was highly successful in India. It upgraded the status of country from a 'technology-laggard' to a 'technology-follower' nation. This suggests that imitation practices do not necessarily indicate the weakness of the firm, industry or nation. Depending upon the context, imitation may lead to competitive advantage related to the time, cost and risk involved in innovation, particularly during the 'catch-up' phase. The technology overview in this paper also suggests that there has never been one single technology paradigm and trajectory for pharmaceuticals. Rather there are parallel paradigms and trajectories. There has been a vast difference between the trajectories adopted by the firms in India and in the developed countries for growth and technology development and public policy has played a key role in shaping them.

The chronological review of policy and technology evolution also suggests that policy has had different impacts at different times. The policies of the last three decades (from 1970 onwards) were meaningful for their time. However, both policy and firms must co-evolve with the changing external environment and needs of society. Although protection was necessary in the earlier phases of development, as the industry grew, liberalisation in 1991 broadened the horizon for growth and had a positive effect on the overall growth of this industry.

The broad industrial overview in this paper has helped in evaluating the causes and effects of policy in shaping the technology development in the Indian pharmaceutical industry. The paper indicates that an efficient policy-package promotes the creation of new technology and knowledge on the one hand, and on the other facilitates exploitation, assimilation and diffusion of the existing technologies within and across boundaries. Government policies can help foster the domestic research and development (R&D) activities that are needed to build a comprehensive national scientific and technological capacity. From this perspective, now India has a strong installed base for complex drugs and pharmaceutical manufacturing, the changes in the research and innovation practices demanded by TRIPs appear to be a natural and necessary progression for further development of the Indian pharmaceutical industry.

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