

The Indian Pharmaceutical Industry: An Overview

A Challenging Environment

The pharmaceutical marketing environment is perhaps the most challenging one on the Industrial scene today. It is characterized by:

- A. Very intense competition with over 24,000 registered pharmaceutical companies - large, big, medium and small - fighting for their own place under the sun in a rapidly growing market that is estimated to be \$ 55-billion by 2020. The competition is at its fiercest point today.
- B. The seemingly ever-increasing and almost never-ending governmental regulations and policy changes.
- C. Stifling price controls, eroding profits and consequently a vanishing bottom line.
- D. Rigorous controls on formulations and an absence of international patent protection resulting in a 'me-too' maze of products with little or no product differentiation.

In short, it is a rat race, where a 'better mouse trap' just will not do. One needs much more than that and as in any jungle-concrete or real, only the fittest survive.

A Brief History

From ancient times, two systems of medicine were vogue in India. Firstly, there was Ayurvedic medicine, which dates back to the Vedic period. Ayurvedic medicine depends largely on the combination of various herbs, minerals and metals like gold, copper etc. Secondly, there was the Arabian system of medicine. Innumerable invasions had brought the Arabian system into India. In contrast to these, two other

systems of medicine, namely Allopathy and Homeopathy, were in vogue in the western part of the world.

Despite being a very advanced indigenous system of medicine, Ayurveda has not really become popular enough, probably because of a very long British rule and the consequent development of an educational system including medical education based on a typical British model. As Allopathy or modern medicine started taking roots in India, all the research and development activities the world over fueled its growth in India as well. Conversely, there was hardly any research and development activities in the area of Ayurvedic medicine. Though the government has been making some efforts to promote Ayurvedic medicine, its development seems to be a long way off. It is still popular in rural areas, mainly because modern medicine has not reached there. In urban areas it has yet to gain importance in so far as the prescription drug market is concerned. The inclination of Allopathic doctors towards prescribing an Ayurvedic medicine is very low indeed. Of late, however, the attitude of consumers towards Ayurvedic medicines seem to be increasingly favorable. Some of the pharmaceutical companies are planning to diversify into Ayurvedic drugs mainly to improve their profitability. Ayurvedic drugs are exempted from price control.

The Indian Systems of Medicine Get A Shot-in-the-arm with AYUSH!

The Government of India has created in March 1995, a department for the Indian systems of medicine (ISM&H). This department was later re-christened as AYUSH in 2003. Ayush means Life in Sanskrit. AYUSH is an acronym that stands for Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homeopathy. AYUSH was later elevated to a ministerial level which formed, The Ministry of AYUSH on November 9, 2014. With this, the Indian systems of medicines are indeed getting the much-needed shot-in-the-arm, which is evident from the progress it has made so far. Here's a snapshot of the progress:

1. There are 627 AYUSH colleges, and four national institutes to impart education at under-graduate level and post graduate level in Ayurveda in India. The national institutes are situated at New Delhi (All India Institute of Ayurveda for Post-graduate education), Jaipur (National Institute of Ayurveda), Jamnagar (Institute of Post-graduate Training and Research), Shillong (North Eastern Institute of Ayurveda and Homeopathy for under-graduate education).

2. The government has also set up five central councils and 82 peripheral institutes or centers for undertaking research in Ayurveda, Unani, Siddha, Yoga and naturopathy, and Homeopathy. These research centers conduct research and collaborative studies in areas such as medicinal plant research (medico-ethno botanical survey, pharmacognosy, and tissue culture), drug standardization, pharmacological and clinical research.

Origin of the Indian Pharmaceutical Industry

It is not exactly known as to when the Allopathic system of medicine made its entry into the country. But it is generally believed that it happened some time during the early part of the 19th century. The medicines were imported by the British for their personal use when they came to do business. This was the beginning of the pharmaceutical industry in India. Later, when they ultimately took over the country, the imports became a regular feature. These pharmaceutical products, which were introduced in India to provide relief to the British, soon gained popularity among the people in urban areas. For the first few decades after their introduction, pharmaceutical products were being imported into the country, mostly from Germany and the United Kingdom.

Indigenous production of these medicines, however, was started in 1901 with the establishment of the Bengal Chemical and Pharmaceutical Works, due to the pioneering efforts of Acharya P.C. Ray. The world of medical treatment was witnessing some significant developments, like Louis Pasteur's discovery of pathogenic bacteria as the cause of infectious diseases, while the Indian pharmaceutical industry was in its early stage. Scientists in India undertook research in tropical diseases like malaria, typhoid and cholera. Between 1904 and 1907 four research institutes, namely The Haffkine Institute, King Institute, Central Research Institute and Pasteur Institute were established. Yet another significant development of this period was the use of chemicals for treating various diseases. Some very important drugs like aspirin and barbiturates were made available during this period. The First World War gave a real stimulus to domestic production of pharmaceuticals. There was a steep rise in demand and a drastic cut in imports. Consequently, the production of quinine salts registered a substantial increase for the first time. Production of caffeine from tea waste and manufacture of surgical dressings were also taken up during this period. However, with the resumption of imports after the war, the

industry was back to square one. It received a set back, as it was unable to compete with imported products.

The Bengal Chemical and Pharmaceutical Works started production of tetanus antitoxin, a basic drug in 1930. Indigenous production till 1939 was sufficient to meet only about 13 percent of medical requirements. Thus a large part of domestic demand for drugs was still met by imports. The Second World War was another landmark in the history of Indian pharmaceutical industry. It provided a propitious atmosphere for further expansion of production.

By 1941, the industry took up the manufacture of new drugs like ido-chloro-hydroxy quinolone as well as a number of alkaloids like ephedrine and codeine. Besides, the industry made a beginning in the production of chemotherapeutic drugs like arsenicals, anti-leprotic drugs and colloidal preparations of calcium, silver, manganese and iodine. The production of glandular products like liver extracts was also undertaken. The Production of several formulations based on imported bulk drugs also showed a significant expansion during the period.

Post-war developments in the west resulted in a high degree of product obsolescence, replacing many older drugs with antibiotics and new chemotherapeutic agents. This put the fledgeling Indian pharmaceutical industry at a great disadvantage. As a result, Indian companies had to stop production of many items that were manufactured during the war years. Instead they started manufacturing formulations based on imported bulk drugs and extraction of therapeutic agents from plant sources.

Thus, at the time independence, with the small base that existed for the production of medicines, the industry could not make much headway, in the absence of consistent governmental support to a nascent industry. The estimated value of production of pharmaceuticals in 1947 was a meagre Rs. 10 Crores.

Post-Independent Era

Immediately after independence, the government addressed itself to the task of achieving a high rate of economic progress with special emphasis on speedy industrialization. When the government of independent India embarked on planned economic expansion about six decades ago, the development of the Indian pharmaceutical industry was not commensurate with the size of the country and the growing needs of its population. Since then, the progress of the pharmaceutical

industry in the country has been substantial and many-sided, and can best be described as dramatic.

Dramatic Progress

From a mere US \$ 31million (equivalent to Rs. 10-Crore in production value) in 1947, to a whopping US \$ 29.1 billion in 2017 (estimated), pharmaceutical industry in India has come a long way. Today India manufactures over 400 bulk drugs and about 100,000 formulations. The number of pharmaceutical units too have increased from 1,752 in 1955 to about 24,000 in 2016. Furthermore, in the United Nations Industrial Development Organization (UNIDO) classification of the developing countries according to the 'state of the art' in the pharmaceutical sector India is ranked at the top.

Exports of bulk drugs and formulations too have shown a dramatic progress from a total import-dependent industry at the time of independence to a net-exporter for over eighteen years now. Pharmaceutical exports have grown from a mere US \$ 24 million in 1965 to a net-exporter status in 1999-2000 with an impressive US \$ 1.25 billion in 1999. Total exports of pharmaceuticals in 2016 were US \$ 16.6 billion.

Industry Structure

The pharmaceutical industry is very aptly described as a 'life-line' industry. It plays a vital role in alleviating the suffering of millions of people and controlling various ailments that afflict human beings. Recognizing this, the planners of Indian economic development after independence have rightly included this industry in the core sector.

The present day Indian pharmaceutical industry has three main sectors:

- 1.** The public sector
- 2.** The Indian private sector
- 3.** The foreign sector

It is estimated that there are presently 24,000 pharmaceutical units with 330 in the list of the Directorate General of Technical Development (DGTD) generally known as the organized sector.

The organized sector, which is less than two percent of the total number of manufacturing units, accounts for about 90 percent of the

total value of drug production, whereas the remaining 98 percent of units account for only 10 percent of production value of drug formulations in the country. In case of bulk drugs, the contribution of the small-scale sector is even smaller.

The Public Sector

Although there are over twenty-four thousand pharmaceutical companies in India, the core of the pharmaceutical industry comprises about 250 large and medium-size pharmaceutical companies of which five are in the public sector. These Public Sector Enterprises (PSUs) are:

1. IDPL (Indian Drugs & Pharmaceuticals Limited)
2. HAL (Hindustan Antibiotics Limited)
3. RDPL (Rajasthan Drugs & Pharmaceuticals Limited)
4. KAPL (Karnataka Antibiotics & Pharmaceuticals Limited)
5. BCPL (Bengal Chemicals & Pharmaceuticals Limited)

The Public Sector Units (PSUs) in pharmaceutical industry started with the first prime minister of India, late Pandit Jawaharlal Nehru. He said: "The drug industry must be in the public sector and I think an industry of the nature of the drug industry should not be in the private sector" But over the years the pharmaceutical PSUs went through a long series of losses, became sick and their rehabilitation and revival plans never took off. Pharmaceutical PSUs have suffered because of policy apathy and it all comes down to the poor management. Jyothi Datta rightly observed in her article that - *Once crown jewels, Pharma PSUs stare into the sunset* in The Hindu Business Line January 20, 2017.

In 2016, a union cabinet meeting chaired by the prime minister Narendra Modi decided to go-head for the need-based sale of the surplus land of four pharmaceutical PSUs to settle outstanding liabilities. Once this is completed, the government would take the steps to close down IDPL, RDPL, and assess BCPL and HAL for a strategic sale.

Research Institutes in the Public Sector

Apart from PSUs, public-funded research institutes also played a pivotal role in the growth of the pharmaceutical sector. The government created a number of research institutes under the guidance of the Indian Council of Medical Research (ICMR) and the Council of Scientific and Industrial Research (CSIR). Both these research institutes played a significant role in boosting the Indian pharmaceutical sector. Here is a

list of some of the more important research laboratories and institutes in the public sector;

1. CDRI (Central Drug Research Institute), Lucknow
2. Indian Institute of Chemical Technology (IICT), Hyderabad
3. National Chemical Laboratory (NCL) Pune
4. Regional Research Laboratories (RRL) Hyderabad, Jammu and Jorhat
5. Center for Cellular and Molecular Biology (CCMB) Hyderabad

In developing few innovative drugs in India, CDRI has made a significant contributions. Many of these, however could not see the light of the day due to lack of commercial orientation. CDRI, however had invented more than 100 new process technologies, which were successfully commercialized.

The significant contribution of CSIR Laboratories in fostering the technological development of the Indian pharmaceutical industry is evident from the fact that a number of Indian drug majors such as Lupin, Ranbaxy, Wockhardt, Piramal, Neuland, Sun Pharma, Orchid, SOL Pharma, J B Chemical and Aurobindo Pharma have benefited from the services of these research institutes in some way or the other.

PSUs and research institutes in the public sector have made another major contribution for the pharmaceutical industry in India, i.e., in the area of human capital. About one-third of the two hundred and odd entrepreneurs who have made the Indian pharmaceutical industry what it is today have worked in IDPL product or research and development in early part of their careers. That is where they acquired the necessary skills and knowledge that are required by the entrepreneurs of pharmaceutical industry and also through their long term association with the public sector units. They form the backbone of the modern pharmaceutical industry in India as we know today.

The Indian Private Sector

What is the major driver behind the spectacular growth of Indian pharmaceutical industry? Cost advantage, skilled manpower, increasing incidence of non-communicable diseases, increasing penetration of health insurance, large number of blockbusters going out off patent in highly regulated markets such as the US and EU (European Union) and the list can go on. But what is the single major factor that enabled

Indian Pharma reach the phenomenal heights that it has reached today? Legislation. Yes. It is the legislative changes that have paved the way for the exponential growth of pharmaceutical industry as seen today. Not convinced? Consider these facts:

- A. At the time of independence, India recognized product patents. There was little or no manufacturing of pharmaceuticals immediately after independence. India was totally dependent on imports from the western world and consequently the drug prices were very high.
- B. 1970. India changed its Patents Act in 1970. The Patents Act 1970 with the Patents Rules 1972, came into force on 20th April 1972 replacing the Indian Patents and Designs Act 1911. One of the major changes of the Patents Act 1970 was giving allowance only to process patents with regard to innovation relating to drugs, medicines, food and chemicals. Indian pharmaceutical entrepreneurs grabbed the opportunity, honed their reverse engineering skills and made in India a major player in the active pharmaceutical ingredients market around the globe in the following years.
- C. 1994. India signed the GATT (General Agreement on Tariffs and Trade) in 1994 heralding a massive opportunity for the Indian industries in general and pharmaceutical sector in particular. Ever-increasing healthcare costs in the developed world have been literally forcing every government to contain costs. A number of blockbuster drugs with multi-billion dollar sales were going off patent throwing up a massive opportunity for generic drugs. Some of the more progressive and ambitious Indian pharmaceutical entrepreneurs have once again lapped up the opportunity and carved out a significant share of the generics market in the US and EU (European Union).

Legislative changes in India have, thus been a great enabler in creating an environment that is conducive to rapid growth. The Indian pharmaceutical sector turned the tables in the domestic market by notching up the top eight slots in the pharmaceutical league table. In the late 1960s and early 1970s there was hardly an Indian pharmaceutical company among the top ten league. In 2017, eight of the top ten pharmaceutical companies are from the Indian sector. Only two multinational companies - Abbott (Rs. 5,851-Crore) and GlaxoSmithKline (Rs-Crore 3,424) could garner a seat at the top-ten table. Top Ten Indian pharmaceutical companies are presented in Table 1.1.

Table 1.1 Top Ten Indian Pharmaceutical Companies

Company	Rs. Crore (MAT November 2017)	Market Share (%)
1. Sun Pharma (including Ranbaxy)	9,729	8.71
2. Cipla	5,069	4.54
3. Zydus Cadila	4,262	3.82
4. Mankind	3,842	3.44
5. Lupin	3,793	3.40
6. Torrent (including Unichem)	3,615	3.28
7. Alkem	3,414	3.06
8. Intas	3,158	2.83
9. Macleods	3,053	3.73
10. Dr. Reddy's Labs	2,500	2.24
Top Ten, Total	42,435	39.05

Source: AIOCD AWACS Pharma Trac

The Foreign Sector

The foreign sector in Indian pharmaceutical industry comprises all multinational companies operating in India. The multinational drug firms had a dominant market share at the time of independence and even till 1970s. Due to legislative and regulatory changes, they later seem to be reducing their focus on the Indian market. The Indian arms of MNC drug firms that have enjoyed premium pricing for many of their parents' innovative drugs even after losing their patent protection may have to bear the brunt of regulatory control, with price controls eating into their profits on one hand and cheaper alternate Indian generics eroding their market shares on the other hand.

The revenues and profits of multinational pharmaceutical companies have been taking a beating since 2013, post implementation of the new drug pricing policy. For instance GlaxoSmithKline Pharma's operating profit margin has dropped from 34 percent in 2010 to less than 18 percent in 2014-15, thanks to price cuts mandated by the new pricing policy. Even the other multinational pharmaceutical companies had a similar experience. The top ten MNC drug firms had a share of 17.37 percent of the Indian pharmaceutical market in 2017, which is less than half of the top ten Indian pharmaceutical companies' share of 39.05 percent (Table 1.2).

Table 1.2 Top Ten MNC Pharma Companies in India

Company	Rs. Crore (MAT November 2017)	Market Share (%)
1. Abbott (Abbott Healthcare, and Abbott)	5,851	5.24
2. Glaxo Smith Kline	3,424	3.07
3. Pfizer	2,689	2.41
4. Sanofi India	2,580	2.31
5. Novo Nordisk	1,233	1.10
6. Novartis	1,069	0.96
7. M S D	756	0.68
8. AstraZeneca	667	0.60
9. Merck	664	0.59
10. Janssen	463	0.41
Top Ten, Total	19,396	17.37

Source: AIOCD AWACS Pharma Trac

Drug Discovery

The record of Indian pharmaceutical industry in the discovery of new medicinal substances is abysmally low. The earliest drug discovered in India was urea stibamine 1922. The second drug was methaqualone, which was synthesized at the Regional Research Laboratories of Hyderabad, had the pharmacological studies conducted at Lucknow and was commercially developed in the U.K. Haymycin, an antibiotic developed by the Hindustan Antibiotics Limited, a public sector undertaking, was the third drug. The fourth drug, enfenamic acid, was synthesized at the Regional Research Laboratories, Hyderabad and was marketed by Unichem under the brand name Tromaril. Ciba-Geigy marketed the fifth drug, an anti-depressant by name Sintamil.

Compared to this, the six developed countries, namely Italy, West Germany, France, the U.K., the USA and Japan had introduced as many as 2,567 new drugs during the ten-year period between 1970-80. During the same period as many as 6,374 new compounds had undergone clinical trials.

Why is it that in seventy years the Indian pharmaceutical industry could not introduce more than a handful of new drugs?

Of course, any comparison with the developed countries is meaningless. But then, India is next only to the two super powers in terms of technically skilled manpower. The research centers are manned

by some of the best scientists. What are the reasons for this dismal performance in discovering new drugs?

- 1. The Cost Factor:** The prohibitively high cost of a new drug discovery is the first and foremost reason. It is estimated that a new drug discovery (from concept to commercialization) would cost on an average about US \$ 1.5 billion, and has a gestation period of ten to twelve years.
- 2. Low Profit Margin:** Large international pharmaceutical companies spend about 10 to 20 percent of their annual sales volume on research and development of new drugs. Most pharmaceutical companies in India would consider themselves fortunate and successful if they could make a 10 percent Net Profit Before Tax (NPBT). Research & Development expenditure in India, therefore, is around an insignificant two percent of their sales volume. However, this is changing as the Indian drug majors are able to make higher profits as they are able to get more than fifty percent of their total sales from international markets, where the price realizations are higher. Some of them are investing close to ten percent of their sales on research to stay ahead of competition.
- 3. Inadequate Fiscal Incentives:** The fiscal incentives provided by the government are hardly adequate to support the high cost of research and development and the risk of uncertainty.

Rapid Strides in Research and Development (R&D)

After India became a member of WTO and product patent regime, some of the leading Indian pharmaceutical companies have stepped up their research and development effort substantially. A Pharmabiz study of 25 drug companies revealed that these companies have increased their research spend by 42 percent in the fiscal 2004 to US \$ 40 million from US \$ 27.2 million the previous year. Companies like Ranbaxy (later acquired by Sun Pharma), Dr. Reddy's Labs, Torrent Pharmaceuticals, Sun Pharma are now spending close to ten percent of their sales on R&D. Furthermore, companies such as Lupin, Zydus Healthcare, Glenmark, Wockhardt too have invested huge amounts on R&D activity and subsequently stepped up their spend on research and development. These companies are improving their competitiveness in areas such as product development, Active Pharmaceutical Ingredients (API) synthesis, Novel Drug Delivery Systems (NDDS) and indeed even in developing new drugs.

Bundle of Paradoxes

The pharmaceutical industry in India provides a curious bundle of many paradoxes. Consider these for example:

Paradox #1: Controlled prices! Expensive drugs!

The industry has been subjected for close to five decades, to an increasingly stringent system of price controls currently covering close to eighty percent of the Indian pharmaceutical market, but the impression is still widespread that the prices of medicines are on the high side.

Paradox #2: Urban industry?

Despite the dramatic progress and the phenomenal growth over the seventy-year period, the benefits of modern medicine have not effectively reached about forty percent of the population. Even today, pharmaceutical industry in India seems to be essentially urban-oriented.

Paradox #3: Healthcare industry ailing?

Despite its apparently impressive overall growth, the industry, which produces drugs and formulations for the health of the people is not really robust, if not actually sick.

The per capita healthcare expenditure continues to be low at US \$ 75 per year. Compare this with Indonesia at US \$ 99 and Thailand at US \$ 228. This per capita expenditure is for the total healthcare. Pharmaceuticals are only 15 - 20 percent of the total health care expenditure. If you take this into account the per capita expenditure on medicines is about US \$ 11.25 - 15 only.

Paradox #4: Small scale or large scale?

Maintenance of high quality standards in the production of both bulk drugs and formula'tions is of paramount importance. Any laxity or compromise in the quality of drugs may spell the difference between life and death. It is common knowledge that many small-scale manufacturers do not possess either the requisite apparatus and equipment or the technically qualified, competent manpower necessary to ensure quality control. They are also not in a position to meet the conditions required for Good Manufacturing Practices (GMP). A number of experts in the field including Dr. B. B. Gaitonde, an eminent pharmacologist and the Regional Advisor of World Health Organization

(WHO) firmly opined that pharmaceutical production does not lend itself to small-scale operations. In spite of unequivocal opinions by experts about the inadequate and unsatisfactory quality of drugs manufactured by the small-scale sector, the units in this sector continue to increase.

Paradox #5: Proliferation of brands or manufacturing units?

It is often argued that there are too many brands, which are not necessary, and this proliferation of brands is leading to wastage of productive capacities, which could not have been used effectively for some other essential products. Secondly, the unhealthy competition between too many 'me-too' brands and the consequent increase in promotional expenditure is pushing up drug prices. Contrary to this popular belief, the proliferation is more in the number of manufacturing units in the small-scale sector that is leading to the ever increasing 'me-too' brands. In 1981, the Drug Controller of India, Dr. S. S. Ghatoskar called for a check on the proliferation of new drug units, estimated to be around 5,000 in 1981 and for a more efficient quality control programs. According to him about one-third of these units are only re-packing units. Ironically enough the number of drug units too have gone up considerably, in fact more than three times to 16,000 by 1992.

Paradox #6: Control costs on output, but not on input costs?

One of the major impediments in the progress of pharmaceutical industry in India is the Drug Price Control Order of 1969 (DPCO). This and the subsequent Drug Price Control Orders have certainly put back the Indian pharmaceutical industry by several years. What is peculiar about the pharmaceutical control is that while the prices of raw materials as well as finished products are controlled, there is absolutely no control on the input costs. The input costs seem to be ever-increasing. As a result, the mark-ups provided in the essential product categories are lower than the breakeven points. To top it all, there is even a ceiling on the profitability of the manufacturing units.

Paradox #7: Retention prices or detention prices?

Another irrational and unrealistic policy is the system of retention prices and the pooling system in case of bulk drugs. Under this system different prices for different manufacturing units are fixed for the same product based on the direct costs and actual yields of the respective

companies. But a 'pooled price' is fixed for the bulk drug to be supplied in the formulations. The more efficient manufacturer who produces the drug more cost-effectively does not enjoy any extra benefit. Instead, he has to deposit the difference between the 'pooled price' and the 'lower retention price' into the Drug Price Equalization Account (DPEA) administered by the government. This amount is used to meet the claims made by the manufacturers (who could not achieve cost-effectiveness due to manufacturing inefficiency), whose retention prices are higher than the 'pooled prices'. Isn't it really a cess pool?

The Chavda Committee has strongly criticized this 'retention and pool-price system' as way of subsidizing cost-inefficient units at the cost of consumer, while penalizing the more efficient producer, who earns only a lower retention price for his efficiency on lower cost of production.

It is a disincentive for efficiency. Why should or why would any manufacturer carry out research and development for improving process efficiency and reduce production costs, when there are rewards for inefficient manufacturing and penalties for efficient manufacturing?

Paradox #8: Licensing policy or silencing policy?

What is paradoxical about the industrial licensing policy, at least in the Indian pharmaceutical industry, is that the policies designed to stimulate growth in production have actually stunted growth. A few examples amplify this:

- Reservation of some essential bulk drugs for the less efficient public sector
- Preference given to the small-scale sector, which cannot hope to achieve the economies of large-scale manufacturing
- Fragmentation of capacities for bulk drug manufacture that is inherent in the licensing policy itself. Bulk drug to formulation ratio parameters of 1:5 or 1:10 virtually force every manufacturer in the organized sector to take up bulk drug production, irrespective of efficiency of operations and consequent cost-effectiveness or ineffectiveness. The net result of all these contradictory policies has been declining profits despite increasing prices.

Paradox #9: Price control or profit control?

Large pharmaceutical companies (with a sales turnover of Rs. 6-crore

or more) cannot earn profits of more than 10 percent of their sales as per the DPCO 1979. Compare this with the R&D expenditure of 10 to 20 percent of their sales turnover by pharmaceutical companies in the developed countries. At this rate can the Indian pharmaceutical industry ever become globally competitive?

The 'Generics' Policy

The government of India announced on January 17, 1981, its decision to abolish brand names for single ingredient formulations, namely Analgin, Aspirin, Chlorpromazine, Ferrous Sulphate and Piperazine and not to permit brand names for all new single-ingredient drugs. In addition, for all other branded-generic formulations, generic names should be printed on packs more conspicuously and above the brand names. The Tariff Commission as well as the Hathi Committee had examined the pros and cons of this new generic policy.

While the advocates of the generics policy felt that a major benefit of the abolition of brand names would be reduction in drug prices, the industry circles contended that in a country where the prices of 80 percent of formulations are controlled by the government the possibility of any further reduction in drug prices is unthinkable. A number of eminent doctors are against the generics-only policy for the following reasons:

- Substitution of drugs by unqualified chemists can lead to dangerous consequences.
- Brand names carry the manufacturer's assurance of quality, abolition of brand names would considerably reduce and weaken this incentive.
- Experience of similar 'generics' policies in some other countries have paved the way for sub-standard and spurious drugs.
- The abolition of brand names for new drugs will prove a strong deterrent to their introduction into the country. The generics policy is likely to benefit only the small-scale manufacturers and traders. The 'generics' experiment in 1980-81 quite clearly blocked the way the new drug introduction. In 1980-81 only 11 new drugs were introduced during the first seven-month period, as against 35 the preceding year.

Wither Loan-licensing?

The government in 1987 announced its decision to phase out and finally abolish the loan-licensing arrangements in pharmaceutical industry by 1990, which was later extended upto 1993, to ensure the adoption of Good Manufacturing Practices (GMP).

But can the government really abolish loan licensing in the pharmaceutical industry? Consider these reasons:

- Loan licensing agreements are not peculiar to India. They are present in many countries such as the US and in Europe. Loan licensing agreements in India have helped the Indian pharmaceutical industry to record very impressive growth particularly during the past four to five decades.
- Phasing out the loan licensing agreements in the pharmaceutical industry would result in closure of about 8,000 small-scale units and about three lakh people losing their jobs.
- Loan licensing system avoids under-utilization of capacities and as a result helps in checking price increases.
- Refuting the allegation that it is the loan licensing manufacturers who are mainly responsible for most of the substandard drugs produced in the country today, the small-scale manufacturers have emphatically stated that such offenses on a percentage basis are more among the medium-scale manufacturers. They had requested government to set up a committee to go into the merits and demerits of the system. A more pragmatic approach would be to enforce stricter quality control parameters and ensure their implementation.

The Policy of Drug Price Control

Price control is the most important issue that the Indian pharmaceutical industry is facing today. While the government after signing the GATT accord, liberalized policies for all other industries in the priority and non-priority areas of the economy, pharmaceuticals have been singled out to be kept under price control as well as licensing restrictions. As a result there has been a steady decline in the profitability.

Mr. T. Thomas, Chairman of Glaxo India Limited (GSK now) in his address at the company's 68th Annual General Meeting, made a

thorough analysis of price control and its negative impact on the pharmaceutical industry in India. He also suggested some plausible alternatives in his speech. The highlights of his speech are given in Table 1.3.

Table 1.3 Price Control: A Policy That Fails

- 1. Fallacy of controlling outputs without controlling inputs:** It is a matter of common sense that if we want to control the price of a product we should be able to control the cost of most of the inputs that go into the manufacture. In order to obtain greater rationality in price control for the items selected, it becomes necessary for government to extend its price surveillance to an increasing number of input industries and services. That is impossible even in a totalitarian state as evidenced by recently exposed economic shambles in the former Soviet Union.
- 2. Inevitability of conflicts of interests and rigidity:** Price control is almost always introduced by government when there is a rise in costs and prices. The politician is more vulnerable when there is inflation, which is precisely the time when the industry will need price increases to compensate for cost escalations. The basic conflict of interest between what is rational and what is expedient, in the minds of administrators of price control and their political masters, introduces a cumulative series of distortions in pricing decisions.
- 3. Quality of products deteriorate to lowest common standards:** Under price control the inevitable reaction of the manufacturers is to survive by adopting the lowest possible standards of services that they can get away with. Companies, which have high standards of quality and safety in the manufacture of drugs prefer to discontinue the manufacture of drugs, which are uneconomical rather than compromise on standards. This inevitably leads to another set of problems that arise from prolonged price controls.
- 4. Shortages, black-markets, black money and spurious products:** As the rigors of price control continue, honest manufacturers will find it unviable to continue the manufacture of products. They will try to minimize their loses by reducing their production. This happened in the soap and vanaspati industries in 1974, and even the government realized the folly of price control on these items and abolished it.

Contd...

Drug companies today are heading towards the same state, that the soap and vanaspati industries were in, in the early 70's. Of late there have been many instances of drug authorities in different states busting racketeers, who were producing counterfeit and spurious medicines. Such racketeers thrive when distortions are caused in supplies due to the rigors of price control. Yet the pharmaceutical industry has been chosen to be the last remaining industry to be still convulsed under price control.

- 5. Small-scale sector is kept outside price control:** The other irrational distortion in drug price control in India is that the small scale sector in the industry is kept outside price control.

In a normal economy, the small scale sector has to compete and justify its existence through lower overhead costs, better quality of service, dedicated nature of relationships etc., and not through subsidies and favorable price discrimination. Subsidization, through discriminatory pricing advantage under a price control regime is not the method to promote a healthy small-scale sector. If the logic of price discrimination in favor of the small scale sector were adopted in more industries, our country would be reverting to medieval times in terms of technology and competitiveness. In any case, how does it benefit the consumer or contain inflation, if the small-scale sector is expected to sell at higher prices while the organized sector is expected to sell at lower but unremunerative prices?

- 6. Erodes resources and motivation to invest in modernization, R&D or expansion:** When an industry is kept under price control, the firms in that industry will not have the resources to invest in expansion, or in modernization and R&D. Every industry, which has been under price control for any period of time, has shown diminishing profits, increasing financial vulnerability and inability to attract fresh investment. In the last couple of years most of the essential industries have come back from the dead after price controls were lifted and are now blossoming and investing in further growth.

- 7. Price control can drive an honest firm out of business:** When price control goes on for long, firms are forced into a choice between continuously compromising on quality while running into losses, or closing the business. This danger of becoming unviable has

already been demonstrated in the case of the Indian subsidiaries of some international pharmaceutical companies. If more companies were to be forced into that situation over a period of time, it could create a shortage or monopolistic supplies by a new breed of manufacturers (as in the vanaspati industry in 1970's) who know how to circumvent price control with scant regard for quality and safety standards. The Indian consumer will be the main loser in that eventuality and the very purpose of government in introducing price control would be entirely negated.

- 8. Price control projects a negative among international investors:** Price control in any industrial sector in a country will act as a major negative factor in the eyes of international investors in general. The negative image caused by price control in the pharmaceutical industry is not confined to investors in that industry alone. Investors generally tend to take a negative view of a government that still maintains its belief in and commitment to the discredited system of price control. The removal of price control is a necessary part of our country's attempt to restore confidence in Indian economic policy and to attract investments from abroad.
- 9. Placing government on collision course with industry:** Price control by the very nature of its administration by government machinery tends to place industry concerned on an inevitable collision course with the government. The most important lesson to be learnt by us in India from the phenomenal success of Far Eastern countries like Japan, South Korea, Taiwan, Malaysia, and Thailand is the co-operative nexus between government and industry in each of these countries. This has contributed to their high performance. Policies and practices that may create conflict between government and industry have to be eschewed if our country has to progress. Price control is one such issue and the sooner it is eliminated from our economy the better will we be placed to create such nexus and effectively compete with other market-oriented economies. When there is such a co-operative nexus between industry and government it secures the interests of consumer as well.
- 10. Price control as a political liability:** When price control is first introduced to a group, it is usually on the basis of populist measures like holding the price line in the face of inflationary pressures. The

rhetoric of the politician at this stage is directed against traders and producers, who are pictured as hoarders and profitters. If by chance there are some international companies engaged in that industry they are branded as 'multinationals' (even though that epithet has lost its venom since the demise of communism in most parts of the world). The minister in-charge almost acts like the brave little Dutch boy, who put his finger in the dyke to stop the leak that could have swelled into a flood.

But as time passes by, the inevitable effects of inflation begin to create strains in the economy and all the ills of price controls begin to show up the shortage, black marketing, spurious products etc., The politician will at this stage try to play the role of King Canute. No tide can pass controllers or ministers, as the tide never respected kings. So they have to concede some price and this assumes a very high profile. Even the pricing of a humble relatively unimportant product like a washing soap was elevated in the 1970's to become a subject matter for the Central Committee of Economic Coordination of the Government of India, presided over none other than the prime minister himself. Today the pricing of multivitamin pills may hold tremors for ministers, who have to take decision. When this stage is reached, the politician begins to feel extremely nervous, like a man riding a tiger. He does not know how to get off the tiger without being eaten alive. On the other hand, he has unwittingly built up a high profile for the tiger and his ride.

But dismounting the tiger of price control requires a lot of skill and some luck. The longer a price control regime for a product continues, the more difficult it becomes to correct or dismantle it. The turmoil being faced by Mr. Yeltsin in the erstwhile Soviet Union in trying to dismantle price control is yet another strong warning against the continuance of price control in our country and calls for the dismantling of existing controls as early as possible.

Need for a Re-look

Cost of production, cost of raw materials, packaging materials, utilities, services, salaries and wages etc., continued to escalate resulting in reduced profit margins. Several leading units suffered losses or just managed to break even. Pharma sales of many companies were in the red with non-Pharma sales subsidizing the Pharma business. The

unmistakable trend in profitability after the 1969 DPCO (Drug Price Control Order) can be seen in Table 1.4.

That the pharmaceutical industry is able to achieve a competitive position in spite of the stringent controls, is a positive proof of what it can achieve with the support of more pragmatic, growth-oriented policies.

NCAER's Observations

While reviewing the ailing Indian pharmaceutical industry's performance, National Council for Applied Economic Research (NCAER) very aptly made the following observations to put it back on the path to growth:

- Preference should be given, in the matter of import technology to companies with adequate research and development facilities to absorb the imported technology.
- To be effective, major part of research and development work on development of technology should be carried out in the industrial units and not in isolated government laboratories.
- To enable the industry to invest more on R&D, its profitability should be improved. Fiscal incentives are of no avail in the absence of adequate profits. Liberal bank credit should also be made available.
- The present restrictions on larger business houses should be relaxed and mergers should be encouraged in order to enable Indian companies to face international competition.
- Instead of sheltering inefficient units and obsolete technologies, vigorous competition between different sectors (public, private organized, FERA (Foreign Exchange Regulation Act), and small-scale sector should be promoted in order to improve the efficiency and bring down prices.
- A more realistic policy may be evolved to enable FERA companies to play a constructive and useful role in the achievement of national objectives.
- From a long-term point of view, a second look is needed at the patent law relating to drugs, as the radical amendments made in 1970 failed to produce any tangible results.

The details of subsequent changes in the Drug Price Control Order and its implications are discussed in detail in chapter on The Price.

Table 1.4 Profitability of Indian Pharma Industry After the 1969

Fiscal Year	Profit Before Tax (% of Sales)	Percent of Sales Sources
1969-70	15.47	Hathi Committee Report
1974-75	10.70	
1977-78	11.70	RBI Bulletins
1980-81	8.80	
1982-83	7.50	
1983-84	6.70	NACER Study
1984-85	5.80	A.F. Ferguson Study
1985-86	4.50	OPPI Estimate
1986-87	3.50	
1986-88	3.40	
1987-89	1.70	
1988-90	2.00	
1990-91	2.00	

Protection of International Patents and Intellectual Property Rights (IPR)

Intellectual Property Rights (IPR)

Intellectual property, as the name suggests, is basically a concept, an idea or thought leading to the actual invention of a product or process. Intellectual property right, therefore, is a legal protection for inventions, which are the results of the individual's ideas resulting in new products and processes. The World Intellectual Property Organization (WIPO) defines and clarifies what exactly should be the nature of 'intellectual property.' Prior to 1994, about 140 countries gave legal protection to both product patents as well as process patents as per the Paris Convention on International Patents and IPR. India along with Mexico, Brazil and China agreed to provide patent protection for products and processes, when they signed the GATT (General Agreement on Trade and Tariffs) at Morocco in 1994.

Patent

A patent is a legal protection for an invention. At the same time, not all inventions are patentable. Generally the invention must possess or meet certain criteria such as:

- It must involve some inventive step
- It must not be obvious, and
- It must be applicable industrially

Inventions can be broadly classified into two categories, namely product inventions and process inventions. The patent too, therefore, could be either a product patent or a process patent or even a combination of both. India, for example, recognizes only process patents since the amendment of the Indian Patents Act 1970.

A patent granted for an invention is an 'intellectual property,' which remains in force for a specific period of time (7 years in India and 20 years in countries, which have signed the Paris Convention of Patents and Intellectual Property Rights).

If any other person exploits the patent without prior authorization (license) of the owner of the patent, he infringes the rights and commits an illegal act. However, if the patentee does not work the patent or he does not allow others to work the same, the patent can be revoked or the patentee is forced to give a 'compulsory license,' which is an authorization to exploit the invention. The conditions of granting a compulsory license are regulated in the Act. The decision of granting a compulsory license includes fixing remuneration for the patent.

Prior to signing the GATT in 1994, India was facing the threat of trade sanctions by the U.S. for its alleged failure to adequately protect IPR. The U.S. government can identify so-called unfair trade partners under a provision named 'Super 301,' of its omnibus trade law of 1988. After naming such countries, the U.S. representative is required to negotiate with them for measures in removing market barriers to U.S. exports including those resulting from alleged theft of patented technologies. If the negotiations do not yield results to the satisfaction of the U.S. government, it can retaliate by restricting or banning exports to the U.S. India was also listed on 'Super 301' category along with Japan, Brazil and South Korea in the early 1990s owing to the pressures exerted by IPR Alliance, U.S. Chamber of Commerce, Pharmaceutical manufacturers, Association of Motion Picture Export Association of America on the U.S. government. The U.S. government has been demanding that India should join the Paris Convention on patents as well as amend the Indian Patent Act of 1970.

Even those who support the demand that India should accede to the Paris Convention admit that it can have disastrous impact on India's

booming chemical and pharmaceutical exports. India's legal luminaries are also unanimous that India should not be a party to a one-sided and discriminatory treaty, which bestows little rights on the signatory, but gives unlimited powers to patent holders.

Signing the Paris Convention on Patents would certainly give a big boost to the multinationals operating in India at the expense of Indian drug manufacturers. The prices of new drugs too, are likely to go up steeply. The domestic industry would receive a severe set back. On the positive side, the newer drugs and the latest discoveries in the field of medicine would be made available in India much sooner than now. The time lag can be minimized and India could benefit fully from the new drug discoveries in the west. More and more multinational companies may be attracted by the opportunities that India has to offer.

Experts opine that the proposed changes (as per the Dunkel Draft) in the Indian Patents Act, which seek to alter the basis of the law from process patents to product patents, would only help patent holders to monopolize commodities and foreclose research. Developing countries would be impoverished and reduced to mere markets for goods produced by developed countries.

Dunkel Draft

Arthur Dunkel, Director General of GATT, has made some compromise proposals in respect of the Uruguay Round of negotiations in the area of Trade Related Intellectual Property Rights (TRIPS). The Dunkel proposals cover a number of aspects like market access, trademarks, product and process patents, term of patent, compulsory license and transitional period.

Transitional Period

All countries save the developing countries have been given a transitional period of one-year and developing countries an additional four years. To the extent that where a developing country not extending product patent protection to the area of technology on the general date of application on the agreement, it has been provided that the developing country concerned may delay the application of the obligation in respect

of patents to such areas of technology for an additional period of five years. Thus in respect of food, chemicals, pharmaceuticals, chemicals and biotechnological products, India will have the possibility of delaying the application of the obligation till 1-1-2003. However, after the date of entry into force, such countries will have to provide means by which applications for patents can be filed. These applications can be examined only when the obligations on patent protection of these products become effective. There is also a provision for exclusive marketing rights for a period of five years, after obtaining market approval for a few products.

Major Objections to Dunkel Draft

The Dunkel proposals were initially objected mainly on the grounds that:

1. Prices of affected commodities would increase substantially
2. Importation being treated as working of the patent would destroy incentives to manufacture
3. A twenty-year patent term would result in delaying introduction of new products
4. Research and development would become redundant
5. Indian exports of such products would be affected
6. Patent protection on biotechnology would have adverse consequences on preventive medicine
7. Automatic licenses of right are needed to bring about competition
8. The burden of proof in case of an infringement should not be on the defendant

Hobson's Choice

Now that almost all countries, including China have fallen in line with the international patent law, it is no longer a matter of choice whether India should be a signatory to the Paris Convention on International Patents and IPR or not. The question is, when should India sign and what changes it can possibly incorporate in the proposed Dunkel Draft? And, how much time can India get for the transition? More importantly, the Indian government should allow drug companies to make adequate profits to prepare themselves to compete internationally.

It is not possible to achieve the ambitious objectives in terms of exports that the Indian government has set for the country in the absence of an international patent protection.

The new world economic order is quite different from what it was even a few years ago. With the ever-increasing trade alliances between different countries, the unification of Germany, the disintegration of the erstwhile super power Soviet Russia, it would be impossible for any nation to function and progress in isolation. The name of the game is cooperation. Furthermore, a number of those countries, which have been important markets for Indian exports are gradually and increasingly recognizing the international patent law. In other words those markets will be closed to Indian exports sooner than later if India did not sign the GATT agreement. Really speaking, it is a Hobson's choice!

India Signs GATT Accord

India after over four years of deliberations, dilly-dallying and protracted negotiations finally signed GATT including TRIPS on 15th April, 1994. This is regarded as a turning point for Indian pharmaceutical industry.

The main impact of TRIPS on pharmaceutical patents in India are:

1. A patent term of 20 years from the date of filing
2. Recognition of product patents
3. Importation of a product to be accepted as 'working' a patent
4. Compulsory licensing to be confined to special circumstances like emergency or abuse of patent rights
5. Reversal of 'Burden of Proof' in infringement action relating to process patents (obliging the defendant to prove that the process is non-infringing)

Transitional Period

The adoption of these provisions would bring Indian patent laws close to those in the industrialized world.

However, there will be a considerable delay before the effect of fundamental changes are perceived. Like all other developing countries that have not until now (1994) recognized pharmaceutical and technology products as patentable, India too is entitled under the terms of GATT agreement to a transitional period of ten years, before

having to adopt to product patents for drugs. The transitional period for India was from 1995 to 2004.

Further, there would be no product protection for pipeline drugs (drugs under development during the period under patents published elsewhere in the world).

Indian companies that currently produce drugs that would infringe a product patent, if such a patent were recognized by the government or will infringe an international product patent prior to 2005 (pipeline drugs), may continue production after 2005, provided an equitable royalty and license fee is given to the originator till the patent expires.

Exclusive Marketing Rights (EMR)

However, drugs for which patent applications are made after TRIPS came into effect will have some marketing exclusivity in India, if they are registered during the transitional period. This exclusivity will run for a maximum period of five years during the transitional period and thereafter until patent expiry.

Implications of GATT

The signing of GATT is a mere signal that heralds a major change in the business environment worldwide. The protected markets are in the process of being snapped. The markets will therefore, be fiercely competitive. Only the fittest of industries will survive.

Once the transitional clock starts ticking, things will never be the same again. Dramatic changes are ahead for the Indian pharmaceutical industry. Some of the more important changes are:

More Active Multinational Companies (MNCs)

1. End of the era of protectionism under the Indian Patents Act (1970), a key factor that helped the Indian drug companies to achieve a remarkable rate of growth and even a net-exporter status in the Pharma industry.
2. The nature and intensity of competition are likely to change significantly. Multinationals will be more active in India as they ride out the transition period before GATT comes into force.
3. There will be a total restructuring of operations to optimize product lines and to introduce newer drugs in the Indian market. Some of the multinational drug companies introduced new products,

after India signed the GATT agreement. They have been holding back these product introductions. Some of these companies are: Bayer (Adalat Oros), Hindusthan Ciba Geigy, which is Novartis now (Nitraderm Transdermal product) and Sandoz, which is Novartis now (Sandimmune Neoral).

4. Some multinationals might want to get out of manufacturing in India altogether and concentrate on marketing and licensing their products. Already some of the well known international drug majors such as Hoechst (now Sanofi Aventis), Glaxo (now GlaxoSmithKline), Hindusthan Ciba Geigy (now Novartis) have already been into third-party manufacturing for greater flexibility and profitability (lower manufacturing costs).
5. Exports of new bulk drugs will no longer be that easy. First of all, cheap manufacturing of new bulk drugs will not be possible with product patents. Secondly, many bulk drug manufacturing facilities were coming up in South East Asian region posing tough competition to Indian exporters. Tough times indeed for small and medium players and the only way out is partnering with larger Indian companies or even multinationals.
6. While the fragmentation in the domestic industry continues due to the encouragement given by the government to small-scale manufacturers, there would be some contraction as well as consolidation through takeovers by larger companies wanting to increase their capacities. Those with good manufacturing facilities and practices would become toll manufacturers for large national as well as multinational companies.
7. The passage of Indian companies from a drug 'copying' culture to a 'research-based' strategy, each with its own aspirations to eventual multinational status (e.g., Sun Pharma, Lupin, Dr. Reddy's Labs, Wockhardt, Cipla etc.).

Future Position

The bigger gain from TRIPS is qualitative in nature. The transition to a regime of product patents will result in global majors entering India in a much bigger way with R&D intensive technology. India already possesses the necessary technological infrastructure for original R&D. As Dr. Heinz Redwood, author and Pharma industry consultant from U.K. says, "It is not scientific genius that is in short supply, but cash flow."

Action Agenda

Ten years may seem long so far as transition is concerned, but it is no more than the average time it takes to develop a newly patented drug

to the point of market introduction. The need, therefore, is to adapt business strategy to cope with the reality of product patents. The action agenda of some of the more progressive Indian companies focuses sharply on:

- A.** Reaching a critical mass
- B.** Marketing focus
- C.** Upgrading technologically
- D.** Increasing investment levels in R & D significantly above the industry average
- E.** Shifting of emphasis on export thrust from bulk-drugs-mainly to move value added generic formulations and to even more value-added marketing of branded generics overseas
- F.** Strategically integrating backwards into key bulk drugs and intermediates to achieve control on inputs in terms of cost, availability and quality
- G.** Improving efficiency of operations through optimization of business process and re-engineering

The Changing Face of Indian Pharmaceutical Industry: Post - WTO Era

A number of leading Indian pharmaceutical companies have seen a wide opportunity in the Post-GATT era before it arrived. They have seen at least seven big opportunity areas that can be exploited as India integrates with the world economy by recognizing product patents. Here's the rainbow on the opportunity horizon, which these companies have envisioned:

1. Marketing of branded generics in the domestic market
2. Marketing of bulk actives and drug intermediates in the highly industrialized regulatory markets
3. Marketing of branded generics in countries with little or no IPR protection
4. Marketing of generic formulations of off-patent drugs in regulated markets with strong IPR protection
5. Opportunities for custom synthesis of newly patented molecules
6. Branded generic formulations of off-patent, yet single-source drugs that are difficult to copy
7. Contract research opportunities

Furthermore, they have even visualized that in the not-so-distant future, there would be opportunities for collaborative research including

drug discovery. Their vision and dreams have become a reality thanks to their valiant efforts and some positive policy initiatives by the government of India. As a result, within a decade after joining the World Trade Organization, Indian pharmaceutical industry has achieved a dramatic progress exploiting all the opportunities that globalization has to offer and more. Table 1.5 provides a snapshot of the dramatic progress that Indian Pharma industry has achieved on several counts.

Table 1.5 Dramatic Progress of Indian Pharma Industry: A Snapshot

Area	Progress Made
1. APIs (Active Pharmaceutical Ingredients)	<ol style="list-style-type: none"> 1. India became the third largest global API merchant market with a market share of 7.2 percent. 2. World leader in terms of Ys (Drug Master File) applications filed in the US.
2. Formulations	<ol style="list-style-type: none"> 1. Largest exporter of generic drug formulations in the world with a 20 percent share of the export market. 2. Ranks second in terms of the number of ANDAs filed with the US FDA
3. Manufacturing	<p>Very competent and competitive manufacturing infrastructure comprising:</p> <ol style="list-style-type: none"> A. 584 manufacturing sites certified by US FDA B. 1,400 WHO GMP certified manufacturing plants C. 1,105 manufacturers with COS (Certificate of Suitability) from EQDM
4. CRAMS (Contract Research and Manufacturing Services)	<ol style="list-style-type: none"> 1. India's share of the global CRAMS market is likely to increase to 8-9 percent by 2018 2. Indian companies operating in contract manufacturing segment are moving up the value chain and are investing in better technology and higher capacities. Global majors are likely to outsource value-added products for biotech and speciality therapy areas from Indian companies operating in CRAMS space. (Contract Research and Manufacturing Services).

Contd...

5. Bio-similars	<ol style="list-style-type: none"> 1. The Indian Bio-similars industry has been growing at CAGR of 30 percent. There are currently 25 companies operating in this space, marketing close to 50 products. 2. The global Bio-similars market is projected to be between US \$ 25 to 35 billion. 3. The early experience with developing Bio-similars is paving way to capitalize on unfolding this big global opportunity.
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Source: Adapted from IBEF

Exports

Indian pharmaceutical companies have been capitalizing on export opportunities in regulated and semi-regulated markets for some time now. In 2017, India exported pharmaceutical products worth US \$ 16.84 billion and this is expected to grow to US \$ 20 billion by 2020. For a country that was totally import dependent at the time of independence, to US \$ 16.84 billion in 2017 is a very commendable progress indeed. The progress of Indian pharmaceutical exports and the consequent reduction in imports is presented in Table 1.6.

Table 1.6 Progress of Indian Exports (US \$ Billion)

Financial Year	Exports	Imports
2012	10.1	3.6
2013	12.6	4.4
2014	14.5	4.6
2015	14.9	3.7
2016	16.9	3.7
2017	16.8	NA

Source: Adapted from Pharmaceuticals, IBEF, February 2018

Indian pharmaceutical industry today has achieved the distinction of becoming the world's largest provider of generic medicines. India accounts for about a fifth of the total global exports of generic drugs in terms of volume. These achievements have earned India the sobriquet - '*the pharmacy of the world*'. Indian drugs are exported to more than 200 countries in the world, with the US as the key market. Table 1.7 presents details of Indian drug exports by region.

Table 1.7 Indian Drug Exports: Key Destinations

Region	Percent of Total Indian Drug Exports
US	40.6
Europe	19.7
Africa	19.1
Asian Countries	18.8

Source: Adapted from Pharmaceuticals, IBEF, February 2018

The two major contributors for achieving this leading position in pharmaceutical exports are legislative in nature. The first one is the Indian Patents Act 1970. It has brought the process development and reverse engineering skills of the country in organic synthesis to the fore. This technological capability has propelled Indian bulk drug industry to the third largest global generic API (Active Pharmaceutical Ingredient) merchant market in 2016, with a market share of 7.2 percent and massive portfolio of over 400 bulk drugs. In addition, India today is the world's leader in terms of Drug Master File (DMF) applications with the US, the world's largest pharmaceutical market.

The second major contributor is its signing the GATT (General Agreement on Tariffs and Trade) in 1995. It has brought the superior product development and manufacturing capabilities of the Indian pharmaceutical industry to the forefront. Indian pharmaceutical industry today capitalized on the tremendous opportunities that globalization has to offer and built a huge manufacturing infrastructure of 546 US FDA approved manufacturing sites, the highest number outside the US. Interestingly Indian drug makers account for close to a third (30 percent) of all the ANDAs (Abbreviated New Drug Applications) in the US.

The spectacular growth of the Indian Pharma industry seems to have come to a grinding halt in FY 2016-17. The exports during the year were more or less static at US \$ 16.84 billion. The main reasons for this no-growth situation are - price erosion and absence of blockbuster drugs for Indian Pharma players. While this is a matter of concern, it is not alarming. Indian Pharma industry is strong and capable to meet any challenges that the changing global environment may bring.

Research and Development

Historically Indian pharmaceutical companies used to spend on an average 2 percent or less of their sales on research and development. But that has been changing gradually since India joined the World

Trade Organization (WTO) in 1995. Some of the more progressive drug firms in India such as Lupin, Dr. Reddy's Labs, Sun Pharma among others have been increasing their R&D spend. The R&D spend by five top Indian pharmaceutical companies is presented in table 1.8.

Table 1.8 R&D Spend by 5 Top Indian Pharma Companies
(Rs. Crore)

Company	F Y 2010 R&D Spend	F Y 2010 R&D Spend as % of Sales	F Y 2017 R&D Spend	F Y 2017 R&D Spend as % of Sales
1. SUN Pharma	208.2	5.5	2,145.8	7.1
2. Lupin	343.8	7.2	2,310.0	13.5
3. Dr. Reddy's Labs	379.3	5.4	1,955.0	13.9
4. Cipla	228.1	4.3	1,071.0	7.5
5. Aurobindo Pharma	97.2	2.7	543.0	3.7

Source: Bloomberg

The R&D expenditure of the top five Indian drug companies has increased six-fold since F Y 2010. The R&D expenditure as can be seen from the above table constitute 9 percent of the cumulative revenues of these companies. In fact, research costs of these companies are comparable to their global peers such as Teva, Mylan and Allergan.

As a result of this increasing R&D effort, India, which has been known for the past fifteen years or so as a large exporter of APIs and generic formulations is now getting to be known for a little more than that - an emerging hub of pharmaceutical research and development.

Companies such as Dr. Reddy's Labs, Sun Pharma, Zydus Cadila, Glenmark, Lupin, Wockhardt and Cipla and a few others have been, besides building on traditional generic product pipelines, investing in research on complex generics, specialty and differentiated products. They also started investing in pre-clinical development of small molecules with novel targets and with novel mechanisms of action. Indian Pharma and Biotech companies have been able to pile of an array of more than 120 new chemical entities (NCEs) currently under various stages of pre-clinical and clinical development.

Inadequate Follow Through

As aptly observed by Dr. Makarand Jawadekar, the most monumental event in the history of pharmaceutical R&D occurred in 2005, when the country signed a new patent law as a part of joining the World Trade Organization. While this event opened the flood gates for pharmaceutical innovation in India, the follow through has not been adequate. Consider these reasons for example:

1. India continues to lack the required amount of domestic private investments as well as the academic collaborations.
2. Aggressive price controls, while improving the access to medicines, reduce the profitability and consequently their ability to invest in research and development. This stifles innovation.
3. Inadequate respect for intellectual property is slowing down the progress of India's R&D sector from making a complete transition from a generic market to a patents market.

Positive Features

While the follow through could have been better after the momentous decision of joining the WTO, the progress of pharmaceutical industry is not without positive features. Take for instance the Gross Domestic Product (GDP) of India is expected to grow by 5 percent each year for the next four decades. The economic growth coupled with its changing epidemiological profile with cardiovascular problems and other chronic diseases and availability of technically qualified and competent manpower make India a strong candidate to become an important hub for pharmaceutical R&D and manufacturing.

In addition, two governmental initiatives such as continuous improvement in healthcare infrastructure and its strong intent in making India a hub for pharmaceutical innovation at least in Southeast Asia with multi-billion dollar investment with 50 percent public spending will help Indian pharmaceutical industry in achieving strong global presence even in innovative space.

The Indian pharmaceutical industry is well positioned to surpass other BRIC (Brazil, Russia, India, and China) in the 21st century as a global hub for end-to-end drug discovery and innovation. What is needed is a well-thought out and rational policy for Intellectual Property Rights (IPR). Clarity on patent law and its enforcement are essential not only to make Indian pharmaceutical industry shine, but even for its viability.

Generics-Only Policy Revisited

Prime minister Narendra Modi said in April 2017 that the government was looking at a law that ensures doctors prescribe medicines only by their generic name to improve affordability and accessibility of medicines in a country of 1.2 billion people, where majority live on less than US \$ 2 a day. Nilesh Gupta, managing director of the Indian drug major, Lupin echoed the views of the Indian pharmaceutical industry when he responded to Modi's announcement: "Generics are fine, but there has to be a proper rigorous mechanism to enforce quality, like in the US. Unless India evolves on that, it will be disastrous".

The idea of generics-only is not new. India is not prepared to implement a policy of generic prescriptions only. Consider these reasons:

1. Half the Indian pharmaceutical market is made up of combination drugs and it would be impractical to ask doctors to prescribe series of chemical names.
2. Such a 'generic prescriptions only' policy puts too much power in the hands of chemists, most of whom are not adequately qualified.
3. Chemists would dispense the drugs on which they get the highest margins. They are unlikely to pass on the discounts to patients.

Here are two blog posts (Tables 1.9 and 1.10) from buildingpharmabrands.com that explains clearly why a generic prescriptions only in India would not be appropriate.

Table 1.9 Evolution or Devolution?

Evolution or Devolution?

Medical Council of India (MCI) and the Indian government are aggressively promoting the use of generic drugs. Pharmabiz wrote in an article titled *Medical Council of India asks doctors to prescribe drugs with generic names*, on May 10, 2013. That the MCI has issued circulars to the deans of all medical colleges, directors of Post Graduate Institutes and presidents of state medical councils to give wide publicity to ensure compliance by doctors to the clause 1.5 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002.

Branded Generics to Generic-Generics?

One hears more often these days that going generics is the way to improve access to medicines. The recent wins of patent cases

against a few of the anticancer drugs and an approval of a generic version of an MNC's anti-diabetic drug have only furthered the case for generics. Is generic prescribing a better option? Which is the logical way or a path for a branded-generics pharmaceutical industry that is poised to evolve into a research-based drug industry in future? Become a generic-generics drug industry? Would that be an evolution or devolution?

Two Assumptions

The popular themes about promotion of generic prescribing are based mainly on two assumptions:

A. It will reduce prices and improve access to medicines considerably

B. It will significantly reduce the corrupt prescribing practices

Let us examine the first assumption that generics-prescribing leads to considerable reduction in drug prices. This is more relevant to the highly regulated first-world markets such as the US, Western Europe and Japan where research-based pharmaceutical industry rules the roost. In these patent-protected markets when the patents of drugs expire, a number of generics are introduced bringing down the prices considerably depending upon the generic penetration, almost by eighty to ninety percent of the innovator-drug prices within six months of genericization.

In branded-generic markets like India, where the prices are already at 20 to 30 percent of the innovator-drug prices, a significant price reduction is unlikely to almost ninety percent of drugs as they are off-patents already. In case of new drugs the government can regulate the prices in a number of ways taking into account the socioeconomic conditions of the patient populations.

Can the generic-prescribing reduce the corrupt prescribing practices? Think for a moment what is the root cause of this problem. When you look at the hierarchy of pharmaceutical products, innovator or brand-name drugs are at the top with the maximum product differentiation, which enables them to command a price premium. Next in the pecking order are value-added generics such as drug delivery products of the same molecule with a perceptible and patentable degree of differentiation, which helps them get some price premium. Branded generics are next in the line with a lesser degree of differentiation in terms of quality perception, availability, customer service etc. Generic-

generics are at the bottom with a commodity status with virtually no differentiation. When there is no product differentiation, gratification rules the strategic roost. That explains but doesn't justify the unabated corrupt practices by drug manufacturers in wooing the prescribers.

The prices of branded-generics and generic-generics do not vary significantly in branded generic markets such as India. The prices to retailers and hospitals may have hefty discounts, which are not passed on to patients entirely. Patients pay almost the same price while the channel members get increased margins.

Evolution or Devolution?

The modern pharmaceutical industry as we know it today has evolved over many years and contributed significantly in the discovery and development of drugs to cure many diseases that were thought untreatable. The same industry has to develop even the future cures. Therefore, it has to continuously evolve. The evolutionary path for a research-based pharmaceutical industry has been an arduous one. A firm would start off as an API manufacturer or a generic-generic manufacturer and move up the evolutionary road to become a branded-generic manufacturer to international generics manufacturer and further move up to a value-added generics to specialty Pharma and finally to a research-based pharmaceutical industry. The Pharma companies need to generate an investible surplus to move up at every stage. With each forward step during this evolutionary process, the company would be creating and increasing its ability to differentiate itself from the rest of the pack.

Going back to generic-generics is devolution or backward-evolution. De-evolution is the notion that a species can change into a more primitive form over time. In terms of modern biology, the term may be a misnomer for that concept as it presumes that there is a preferred hierarchy of structure and function, and that evolution must mean progress to more advanced organisms. However, in the context of modern pharmaceutical industry and the state and stage at which the Indian pharmaceutical industry is currently positioned going from branded generics to generic-generics instead of moving towards a research-based pharmaceutical industry is clearly devolution. It is, if not going back to primitive stage, it is likely to become primitive in future by standing still at the present stage in its present state, while the rest of the pharmaceutical world is moving forward.

Table 1.10 Are We Aligning or Are We Aping?**Are We Aligning or Aping?**

The Drug Controller General of India (DCGI) has stated that manufacturing licenses will only be issued based on generic or chemical names, and not on brand names. Archana Shukla (Asst. Editor, Rural affairs and Pharmaceuticals at CNBC and TV 18 recently reported that industry is divided on whether this is fan indicator of the government's move to push generics eventually banning the brand names for drugs.

The matter seems to have been clarified with the DCGI (Drug Controller General of India) at least for the time being as stated by the Indian Pharmaceutical Alliance's secretary general, DG Shah. The main aim of this circular is to align ourselves to international standards and separate manufacturing licenses from trademarks. It is a step to deal with the similar-branding issues, as many brand names sound similar for a number of drugs which are currently in the market. It is not a step to eliminate brand names.

While this ends the ban-on-brand-names-for-drugs speculation, a number of questions and concerns remain. The government has ordered the public sector doctors to prescribe only generic names and not brands. In a country where over 90 percent of the drugs consumed are branded generics how can the move from branded generics to generic-generics is possible? Not only that, most of the country's pharmacies are staffed by unqualified personnel. How will they dispense chemical names and contend with difficulties of this change? Furthermore, more than 50 percent of the drugs currently used are combination drugs. How will the doctors prescribe a combination drug as a generic?

There is more to international standards than merely changing over to generic prescriptions. The entire eco system of the highly regulated markets is different. In the US, which is the biggest market for generics there are innovator drugs or brand-name drugs, branded-generics and generic-generics. The prices of brand-name drugs are out of price control as the drug discovery costs and risks are very high and the drug companies have to recover the investments before their

patents expire. The first-to-file and first-to-enter the market generic drugs too have a window of 180-days of exclusivity during which period the prices are much higher than the generic-generics. The prices of generic-generics of course would be much lower.

The next question concerns the quality of the generics. There are not so many generic variations after the patent expiry. There are very stringent quality control measures to ensure that the generics are effective in treating the patients. Every generic drug should submit a bio-equivalence test comparing it with the innovator drug as they believe that therapeutic equivalence is important and chemical equivalence does not necessarily mean that it is therapeutically equivalent. Moreover, the generic applicant should conduct this test at the US FDA approved laboratory only. All this costs a lot and puts an entry barrier for fly-by-night operators.

Contrast this with the current scenario in the Indian drug regulatory environment. The technical infrastructure is not comparable and is not ready to ensure all these quality issues. Many of the reported close-to-ten-thousand drug companies do not have a manufacturing facility that conforms to and approved by WHO GMP (World Health Organization's Good Manufacturing Practices). Under the loan licensing system literally anyone with less than a million rupees can start a company marketing his own version of generics. As a result, there are companies competing at international level, national level, regional level and even local level as there are neither any barriers to their entry nor any safeguards to quality.

Yes, it is a level playing field where products with assured quality and not-so-good at quality can survive and have equal opportunities to co-exist! In such a hyper-proliferative market, without adequate infrastructure for testing and checking quality, how will the DCGI ensure that the patients get the same quality of generic-generic that is identical to that of the brand-name drug? A brand-name manufacturer has got his entire reputation at stake. A generic-generic manufacturer who is a recent entrant into the business stands to lose nothing.

All this makes one think and ask "are we aligning ourselves to international standards or simply aping them?"

Loan Licensing Revisited

The government of India took a decision to discontinue loan licensing in pharmaceutical industry in 1986 itself. Loan licensing has served a useful purpose in the past when the multinational companies wanted to get their drugs manufactured in India and market it. The Pharma MNCs utilized the indigenous manufacturing capacity. The Indian manufacturing companies too, gained experience and expertise in acquiring technology. But today, when India is almost saturated with formulation manufacturing capacities, loan licensing does not provide much benefit. Instead it raises concerns regarding quality maintenance and assurance.

The government of India, therefore, once again decided to phase out loan licensing in its 2017 draft policy pharmaceutical industry except in biopharmaceutical sector. This is because, the stage of development in biopharmaceutical sector in India is currently similar to the formulations in the 1980s.

The 2017 Pharmaceutical policy states that loan licensing will not be allowed, except in the case of biopharmaceuticals. The policy anticipates some resistance by the industry players and has a plan B, which includes:

1. Phasing out loan licensing in three years
2. Allowing loan licensing on WHO GMP-approved facilities only
3. Allowing upto 10 percent of the company's total production

Industry stakeholders however, argue that discontinuance of loan licensing makes the installed capacities of small and medium enterprises (SMEs) redundant. What is more, it is estimated that today about 40 percent of pharmaceutical production is generated through loan licensing model. If loan licensing is discontinued, the burden on local pharmaceutical companies would dramatically increase as these companies will have to invest in Capex plans. They may have to acquire these SMEs into their fold.

P2P (Product to Product) Manufacturing

There is another variant of loan licensing that is currently in practice by various pharmaceutical companies. It is P2P or product to product manufacturing. Under this scheme, one company is approved to

manufacture the product for different companies, who will then market it under their respective brand names at varying prices.

This system has led to mushrooming of regional marketing companies across the country with multiple brands that add little or no value. A number of companies which have spare manufacturing capacity manufacture a number of 'me-too' products to individuals including doctors on a batch by batch basis for marketing under their own names. This so-called franchisee-system (another name for P2P) is also responsible for increasing the unethical marketing practices. Such regional marketing outfits on a franchisee system are reducing the ethical prescription drug business (prescription drugs used to be called ethical drugs in the past) to a crass commercial system that is discount and commission based between the marketers and prescribers.

The new drug policy aims to phase out the P2P practice, following the broad principle to have one manufacturer, one salt, (active pharmaceutical ingredient) one brand name and one price.

Compulsory Licensing

Compulsory license is an authorization given to a third-party by the government to make, use or sell a particular product or a particular process, which has been patented, without the need of the permission of the patent owner. Compulsory licenses, therefore work against patent holders. But then, they are given only in certain cases of national emergency and health crisis.

There are certain prerequisite conditions, which need to be fulfilled if the government wants to grant a compulsory license in favor of someone. At least three years should pass from the date of grant of patent before anyone interested to make an application to the controller for grant of compulsory license on any of the following three conditions:

- A.** That the reasonable requirements of the public with respect to the patented invention have not been satisfied or
- B.** That the patented invention is not available to the public at a reasonably affordable price or
- C.** That the patented invention is not worked in the territory of India.

Thus, the use of a compulsory license effectively withdraws a patent from a drug completely if it is seemed prohibitively expensive to a domestic market and a vital public health need.

The first-ever and only case of compulsory licensing case (case 1.1) in India is a landmark case. It is the case of Natco Pharma, an Indian generic drug firm and the German Pharma giant, Bayer Corporation. It explains clearly the philosophy and the rules behind that guide the compulsory licensing decision.

Case 1.1 Natco Pharma Gets the First-Ever Compulsory License for Generic Nexavar In a Landmark Decision!

Bayer, the German Pharma major invented Sorafenib (brand name: Nexavar) used in the treatment of primary kidney cancer and advanced primary liver cancer and priced it at Rs. 2.80 lakh for one-month's supply of the drug (120 tablets) in India. The price being exorbitant, the drug reached only 2 percent of the patient population.

Natco Pharma, an Indian generic company requested Bayer for voluntary license to manufacture and market the drug in India, which Bayer denied. Natco, then filed application with the Controller of Patents for grant of a compulsory license of the drug, Sorafenib. The Controller granted compulsory license to Natco to manufacture and sell a generic version of Nexavar under the following conditions.

- A.** Natco would pay a 6 percent royalty on the net sales every quarter to Bayer.
- B.** Further it could only charge Rs. 8,800 for a monthly dose of 120 tablets of the drug and
- C.** Donate free supplies of the drug to 600 needy patients each year.

The Controller of Patents granted compulsory license in this case as he found that all the three criteria for the grant of a compulsory license as per Indian Patents Act were satisfied.

- 1.** Bayer supplied the drug to only 2 percent of the patient population and the reasonable requirements of the public with respect the patented drug were not met.

2. Bayer priced the drug exorbitantly high at Rs. 2.80 lakh for a month's supply of the drug. It was unreasonably high as it was many times more than the per capita income in India in 2011. The per capita income in India in 2011 was US \$ 1,575 where as the cost of the drug per year was US \$ 69,000. Compare this with the price of Natco's generic version of US \$ 2,120.
3. Bayer did not sufficiently work the patent in India.

Later, Bayer challenged the order passed by the Intellectual Property Appellate Board (IPAB) in Bombay High Court, which upheld the IPAB Order.

Later, on April 2013, Indian Supreme Court gave a ruling that rejected a patent of another Big Pharma company, Novartis for its leukemia drug, Glivec after a six-year legal battle stating that small changes to its earlier version of the patented drug did not deserve a new patent.

Both rulings are landmark cases and have been vehemently criticized by both Big Pharma and countries, where these companies were headquartered. India, however, did not break any rules in both these cases. Its verdicts are allowed under TRIPS (Trade Related Intellectual Property Rights). It's just that no country previously dared to take such a path breaking step. What is significant now is that it is a global trend. Christian Mazzi, a partner with the New York-based international consultancy firm, Bain & Company made an interesting observation when he said:

Historically, governments have protected themselves...by preventing access to the market or by controlling price, but never by controlling patent protection. This is the next wave, if you will. And this goes to the very core of the pharmaceutical business model on their virtual monopoly created by patent protection.

But compulsory licensing has not been the only way India has adopted against Big Pharma in an attempt to control drug prices. Indian patent officials have also neutralized Intellectual property protection to some of the Big Pharma companies by not granting them patents. Table 1.11 presents a list of patents revoked by the Indian Patents Office.

Table 1.11 Big Pharma's Patents Revoked in India

Company	Patents Revoked	Reasons
1. Pfizer	Sutent (Sunitinib), a drug used in the treatment of kidney cancer was granted a patent in India in 2007. Sutent was launched in India in 2009 at a price of Rs.1.96 Lakhs for a 45-day treatment. Cipla challenged Pfizer's patent and the Indian Patent Office revoked the patent.	The reason for the revocation of the patent is that it did not have an inventive step.
2. Roche	Valcyte (Valganciclovir) is a drug used for treating active cytomegalovirus retinitis. The condition, if untreated, can cause blindness in patients with HIV infection. Roche was granted a patent for this in India in 2007 and launched it as at a price Rs. 1,042 per tablet. Cipla challenged the patent and offered a generic version of the drug at Rs. 245 per tablet. Indian Patent Appellate Board (IPAB) revoked the patent.	The reason for revocation is that (a) the patent application did not have an, inventive step and (b) Not patentable as increase in bio-equivalence does not necessarily mean improvement in efficacy
3. Merck	Dulera is a combination of three drugs - Mometasone Furoate, Formoterol and Hepta-fluro propane in an aerosol formulation for treating bronchial asthma. Its patent was revoked in 2011	The patent was revoked as there was no inventive step.
4. Bristol Myers Squibb	Baraclude (Etecavir) a leading anti-viral drug used in the treatment of Hepatitis B infection, was pre 1995-molecule for, which no patent was filed in India. Later BMS filed a patent application for its once-daily composition in 2001 and obtained patent in 2011. Natco and Glenmark challenged the patent.	The company has entered into settlement with two Indian generic companies.

Tilting the Balance

Increasing drug prices and consequently the healthcare expenditure is affecting the economies of both developing and developed countries. In developing countries such as India, the issue of drug prices and affordability are even more intense. It is unlikely that the governments in developing countries will be able to resist from their own citizens and patient advocacy groups in favor of multinational drug companies.

Though the objectives of TRIPS is to benefit both the innovator and generic industries in developed and developing nations, the balance seems to be tilted towards the generic pharmaceutical industries across the world as pricing issues take priority in most of the cases.

IPR Climate and Implications for Pharma Industry

India's patent protection is weak and has adverse effects on international pharmaceutical and chemical firms. It is estimated that annual losses to the US Pharmaceutical industry are around US \$ 450-million. (Table 1.12)

Indian authorities have a different perspective. They believe that western governments routinely grant patents for slightly improved versions of medicines whose patents are about to expire and help them to extend their patent lifecycles. In other words they help to evergreen the patents of these products. That enables drug makers to get many patents to upgrade their new, generally more expensive versions rather than the cheaper generic versions. This is despite the arguments of some sections of the society comprising doctors and patients that these patents of marginally improved products do not justify the costs. Some social critics called this ever greening of patents as 'therapeutic fashions'. The big Pharma too is focusing on this analogue research that is patentable and not breakthrough research as such research is becoming very expensive and even unaffordable.

Table 1.12 Major Patent Disputes Over the Past Three Years

Year	Patent Disputes
March 2012	Compulsory license for Bayer's cancer drug, Nexavar (Sorafenib) granted to Natco Pharma
June 2012	Bristol Myers Squibb's Sprycel (Dasatinib) patent infringed
September 2012	Roche's Tarceva (Erlotinib) patent infringement upheld

Contd...

Year	Patent Disputes
November 2012	Patent for Roche's Pegasys (Peg-interferon alfa 2a) is revoked
December 2012	Patent for MSD's combination aerosol dosage form (Mometasone and Formoterol) is revoked
March 2013	Patents of MSD's Januvia (Sitagliptin phosphate) and Janumet (Sitagliptin phosphate and Metformin) are infringed by Glenmark
April 2013	Supreme Court of India upholds patent denial of Novartis's Glivec (Imatinib)
June 2013	The Patent Office denies patent for Boehringer Mannheim's Pradaxa (dabigatran etixilate)
August 2013	Patents of Allergan's Ganfort (Bimatoprost maleate and Timolol) eye drops, and Combigan (Brimonidine tartrate and timolol maleate) eye drops are revoked
June 2014	The Patent Office for the second time denies a patent to US-based Abraxis Life Sciences for their cancer drug, Abraxane (Albumin-bound Paclitaxel injectable suspension)
December 2014	The Supreme Court of India upholds the grant of Bayer's Nexavar's compulsory license
December 2014	Novartis sues Cipla for infringing patents for its respiratory drug, Ombrez (Indacaterol maleate)
January 2015	The Patent Office rejects Gilead's patent application of its Hepatitis C drug, Sovaldi (Sofosbuvir)

India, Indonesia and other developing countries, however have been bucking that trend. They have been denying patents for marginal improvements by Big Pharma companies and licensing local pharmaceutical companies to make generic versions of those drugs, which are affordable to majority of their populations. Indian patent laws are modeled or being considered by about thirty developing countries to ensure rights of their patients. It is this trend that the big Pharma is worried about. If this trend grows and spreads to other countries, the Big Pharma would find it extremely difficult to expand its markets for all the new drugs, irrespective of whether they are marginal improvements or major innovations. It is only natural that the Big Pharma would fight with all its might to prevent the countries in the emerging markets and developing world from shooting down their patents.

India's Tug-of-war with the Big Pharma

Indian Pharma's tug-of-war with the U.S. pharmaceutical companies goes back to several decades, i.e., since 1972, when India adopted the process patents regime. It allowed local drug firms to develop alternate manufacturing processes (through reverse engineering) of existing patented molecules and sell them in the domestic pharmaceutical industry as branded generic medicines. Indian Patents Act 1970 has been the genesis of India's pharmaceutical industry as we know it today. That is the reason why drug prices remain affordable to the common man in the country even today.

The flip side of this was that it encouraged the drug companies in India to continue copying patented medicines and not investing in developing new drugs. That was until India became a member of the World Trade Organization (WTO). Some of the Indian drug majors have stepped up their investment in research and development and even started their drug discovery programs ever since.

What the Big Pharma Wants from India

US-based Pharma MNCs are wary of litigation and generic companies infringing their patents.

Indian laws clearly rule out patents for:

- A.** Molecules invented before 1995
- B.** Incremental innovations and
- C.** Previously known molecules

At least, 500 - 600 patents would have been denied under the section on innovation (Section 3 d) of Indian patent law. Currently, about three-fourths of the 48 patented drugs launched in India are under threat. Five patents have already been revoked and more than 11 are under challenge by way of infringement. Patents on seven more products are entangled in pending opposition proceedings. A patent on Nexavar is already on compulsory licensing.

Alliance for Fair Trade with India (AFTI) said that India did not address many critical and long standing shortcomings to its IPR policy. The big Pharma wants the following things to be changed to make the Indian pharmaceutical market a level playing field both for MNCs and domestic players:

- 1.** Expensive and time consuming patent opposition hurdles for patent applicants.

2. Lack of an effective system for protecting data generated to obtain marketing approval for pharmaceutical, agricultural and chemical products.
3. Adequate protection for IPR holders' interests with respect to patents, copyright and trade secrets.
4. To take meaningful action to revise protectionist, forced localization policies (compulsory licenses, patent revocations etc.) that clearly aim at favoring domestic IP holders at the expense of goods, services and intellectual property from other countries.

Voluntary Licensing (VL) - An Alternate Strategy?

Voluntary licenses, as the name indicates are licenses that patent holders give at their discretion to other parties on an exclusive or non-exclusive basis, the right to manufacture, import and distribute a pharmaceutical product.

Ever since the government of India gave its first compulsory license of Bayer's Nexavar to Natco Pharma, multinational pharmaceutical companies have been rethinking about strategy to launch their new drugs in India. The strategy being voluntary licenses. The details of some of the voluntary licenses that MNC pharmaceutical companies gave to their local partners in India are as follows:

1. MSD Pharmaceuticals gave Sun Pharma an exclusive marketing license for marketing its two patented diabetes drugs - Januvia and Janumet in India.
2. Novartis, a top-ten Big Pharma company enters into a marketing tie-up with Lupin, the Indian drug major for its Onbrez inhaler.
3. Bayer plans to license most of its patented products for India to its local joint venture company, Cadila Healthcare - Bayer.
4. Gilead Life Sciences gave voluntary licenses to seven Indian generic drug manufacturers - Cadila Healthcare, Cipla, Hetero Drugs, Mylan Labs, Ranbaxy, Sequent Scientific and Strides Arcolabs for its blockbuster hepatitis-C drug Sovaldi (Sofosbuvir).

Voluntary licensing to a local partner under mutually agreed terms will not only help patent holders to expand the market but also avoid compulsory licensing action. While government intervention through a compulsory licensing will lead to a drastic reduction in price as it is typically without the consent of the patent holder, voluntary licensing may get a more remunerative price albeit much lower than its original price.

Innovative drug companies with patented drugs realize that voluntary licensing is a wiser option to avoid a likely invocation of the compulsory licensing Act. In addition, a voluntary license offers two advantages:

- A.** A voluntary license helps minimize loss and also ensures a better access of the patented drug to more domestic patients.
- B.** It helps counter one of the most common reasons for issuing a compulsory license - in adequate patient access.

IPR and Its Implications for Indian Pharma

India has achieved a dominant position as the world's leading provider of generic drugs. The country was able to attract sizable foreign direct investment (FDI) in to the pharmaceutical sector and outsourcing of research activities from the Big Pharma companies.

- 1.** Between 2016 and 2017, investment in life sector declined by almost 59 percent from previous years.
- 2.** The country had lost almost US \$ 10-billion worth of investment by not respecting IP norms, stated Mr. Srinivas Reddy, Director, Hetero Drugs, a leading API manufacturer, who holds about 30 percent of global market for HIV drugs.

Achieving Balance

Only twelve compulsory licenses have been granted between 1995 and 2011 across the world, and most of them are for anti-retroviral drugs (ARV) used in the treatment of HIV. India has granted only one compulsory license and rejected two. India has revoked over six patents during this period. Why then this pressure on India to change its IP laws?

How achieve a balance between the two opposing interests of the patients' needs in developing countries and remunerative prices to recover the cost of the drug development in developing countries of the world?

Developing countries such as India should negotiate on pricing with multinational drug companies when it comes to life saving drugs.

The Research-based Pharmaceutical Industry (PhRMA) in the developed world should formulate some strategy for designing drug prices for the developing world so that rewards for huge investments they make on research and innovation do not get diluted.

Understanding the Marketing Environment

To size up and seize the vast opportunities that the Indian pharmaceutical market offers, a proper understanding of the marketing environment of the industry is essential. While the marketers are actively pursuing a strategy of optimizing the marketing-mix: product, price, promotion and place for specific marketing segments, one should bear in mind that many of the forces that influence marketing strategies are outside a marketer's control. These forces constitute marketing environments and exert a powerful influence over the success or failure of a marketing strategy. Marketers, therefore, should develop a clear understanding of and gain insights into these environments. These are:

1. The economic environment
2. The legal and regulatory environment
3. The social environment
4. The technological environment
5. The ecological environment
6. The competitive environment
7. The ethical environment

The Economic Environment

The national and international economic environment affects in one way or another in almost all businesses. Yet, it is the one external environment that you cannot influence. The two principal ways in which the economic environment affects your business are:

1. Its overall condition affects the growth of your markets
2. The financial conditions in the economy affect your ability to raise finances to fuel your projects and growth plans

While it is true that we cannot alter the economic environment, we can certainly make reasonable judgements about its most likely future direction and make decisions that are congenial and consistent with those assumptions.

Once these assumptions have been made explicit, you are in a position to compare them with reality as it unfolds and, when necessary, change your assumptions to match the reality. Remember that classic principle of military strategy - Forewarned is fore-armed!

Key areas to monitor

How does one monitor the economic environment?

You should monitor and keep track of all the vital areas that are likely to affect the market behavior and investment climate. A regular, systematic monitoring of these would give a proper perspective of the economic environment in which you are operating (and will be operating). The key areas to monitor are:

1. Annual growth rate of Gross National Product (GNP)
2. Annual growth in personal disposable income
3. Short-term and long-term interest rates
4. Inflation rate
5. Price / Earning ratio and the industry average
6. Average annual growth rate of the industry as a whole
7. Stock market behavior index

Projecting the Trends

Careful monitoring of these seven vital indicators for the preceding five years and projecting the trends into the next year and further period of five years would equip and enable you better to plan for the uncertain future; to plan a winning strategy and exploit the opportunities, face the threats and meet the challenges.

The Legal and Regulatory Environment

The legal and regulatory environment is another crucial aspect of a firm's environment that impinges on long-term operations and alternatives. Government regulations of business everywhere have been steadily increasing. Such regulations limit the choices that managers can make and may also affect the profitability of proposed projects.

Another area of concern in the legal and regulatory environment comprises the government's attitude toward profits, investment credits, dividends etc. The managers, who evaluate future projects must take all these aspects into account while making assumptions.

The current legal and regulatory environment of pharmaceutical industry is a result of several statutes enacted over a period of more than hundred and twenty years. This statutes or enactments can broadly be categorized into two areas:

1. Those pertaining to quality control of the pharmaceutical industry in India such as quality control, safety and standards of all the drugs manufactured and marketed in the country and those imported into the country. All these are under the purview of the Union Ministry of Health (Directorate General of Health Services).
2. Those pertaining to other aspects of manufacture and marketing

of drugs such as investment, foreign collaboration, licensing of production facilities, pricing, trade marks, patents, import of capital equipment, raw materials and technology. All these aspects were under the purview of different departments like the Ministries of Petroleum, Chemicals and Fertilizers, Industry, Finance, Law, Commerce and Labor of the Central Government. Later, the government of India created a Department of Pharmaceuticals in the Ministry of Chemicals and Fertilizers on 1st July 2008, to provide greater focus for the growth of highly potential pharmaceuticals.

In addition to central laws there are controls and regulations at the state level too. State regulations of the pharmaceutical industry in India can be traced as far back as 1878, when the Opium Act was enacted. Under this Act, possession, transport, import, export and sale of opium was regulated with a view to restricting its use either as a narcotic or as a drug. Poisons Act 1919 was the next regulatory legislation, which empowered the government to regulate the possession and sale of any specified poison and the prohibition of import of any poison except under a license. The Dangerous Drugs Act 1930, the next enactment, vested in the government control over operations relating to all dangerous drugs, including opium.

Some of the more important legislations are listed in Table 1.13.

Table 1.13 The Regulatory Environment of the Pharmaceutical Industry in India

The Regulatory Environment of the Pharmaceutical Industry in India
1. Opium Act 1878
2. Poisons Act 1919
3. The Dangerous Drugs Act, 1930
4. The Drugs and Cosmetics Act 1940
5. The Pharmacy Act, 1948
6. The Industrial Development & Regulation (IDRA) ACT, 1951
7. The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954
8. The Trade and Merchandise Marks Act, 1958
9. The MRTP (Monopoly and Restrictive Trade Practices Act, 1969
10. The Drug Price Control Order, 1969
11. The Patents Act, 1970
12. The Foreign Exchange and Regulation Act, 1973

Consumer Movement

Another important area of the regulatory environment is the consumer movement. Consumer movement is certainly intensifying. Drug Action Committee, Drug Action Forum - while these and other consumer groups, strictly speaking, do not regulate your business directly, they do generate government activity in the affairs of business. Their influence cannot be undermined, nor their importance ignored.

Monitoring the Regulatory Environment

It is obvious that you cannot predict the legal and regulatory environment of your business or for that matter any business. But you can certainly try to make some explicit assumptions about it based on careful observation and monitoring. This can influence positively the strategic plans of your business. Consider these examples:

- The government currently is trying to abolish the loan licensing system in the pharmaceutical industry. The pressure from industry circles has given the loan licensing system a new lease of life for four more years. The reason for the government's decision is to ensure that all manufacturing units implement the GMP (Good Manufacturing Practices). If you are a manufacturer, who is currently manufacturing for a number of other companies on loan license, what are the implications of such a move by the government? A number of alternatives might influence your strategic planning. The appropriate contingency plans are likely to forearm you. In any case, you are likely to be better equipped to meet the challenges.
- According to the Drug Policy 1987, the Drug Controller of India can and most certainly will insist henceforth the clinical research data of every new formulation by every company even if that formulation happens to be a 'me-too' product and an existing one. This is to check the ever-increasing brand proliferation. Till now the companies introducing new formulations of drugs already cleared by the DCI needed only to submit only the laboratory data pertaining to quality control, stability records and the like. The new Drug Policy is going to change all that. A pharmaceutical manufacturer who is alert to changing regulations like these would be better prepared to meet the task of new product introduction.

Key Questions

Correct and appropriate solutions for many a problem depend on the kind of questions you ask. Here is a list of questions, a sort of checklist, for monitoring and appraising the regulatory environment.

1. Will there be more regulation or liberalization in government policy relating to licensing, investment and foreign collaboration of your industry in the next five years?
2. Will there be more or less tax concessions? Duty drawbacks? How will they affect your profitability in the next five years?
3. What are the priorities of the next five-year plan?
4. Will there be more or less government regulations of your production processes in the next five years? What will be its impact on your costs and your competition?
5. Will there be more or less regulation in the next five years of your marketing practices like advertising and sales promotion expenditure, traveling expenditure etc.? How will you respond if there is more government regulation? How will it affect your competitors?
6. How vulnerable are you in facing the attacks by consumer groups regarding your products, their packaging, pricing, distribution, advertising etc.? What steps can you take in preventing any problems? How efficient is your corporate radar in alerting you?
7. What will be your distributors' expectations in terms of trade margins and quality of service? How well are you prepared to meet them?
8. What will be your needs in the area of public relations in the next five years? Have you a systematic plan of action such as goal-setting and measuring your public relations effort?

The Social Environment

Probably, the most significant and difficult to detect changes that will occur in the environment will be social changes. These changes may pose tremendous opportunities for new products and services to the alert, observant, responsive and responsible marketer. Equally, they may produce exceptionally difficult problems to cope with for two major areas, which a changing social environment can affect your business. The

first is the changing composition, attitudes and lifestyles of population. Even if you are an original equipment manufacturer and manufacture for the industry, you cannot ignore the fact that the ultimate market for all goods and services is the consumer. You can certainly be affected through changes in the demand for various consumer products (and services). Consider for a moment the fact that children below 14 years account for about 40 percent of the population today. Does it not suggest a large pediatric market? It is a small wonder that demand for pediatric products has been increasing during the recent past. The demand for baby care products, toys, books, baby foods, schools, teachers, primary immunization, pediatric dosage forms of pharmaceuticals and indeed even for pediatricians has been on the increase for the past few years. Consider the ripple effect of the increasing literacy levels and the awareness of family planning at least among the urban population. The changing scenario is not difficult to visualize. Smaller-urban families, working couples open new markets like children's day-care centers, and expand the demand for many up-market products, like convenience foods, labor saving appliances etc.

In a few years, the present pediatric market will be changing to the 'youth market'. Consequently, there will be a shift in demand to sports goods, fashion clothes, colleges, personal computers, laptops, smart phones, hi-fi equipment, fitness centers etc.

Also, consider the increasing segment of senior citizens in the country. In the U.S. for example senior citizens account for the largest chunk of the disposable income. That is why many marketers have been specifically targeting their products toward this hitherto neglected segment. While graying Indians are not currently as fortunate as their U.S. counterparts, at least in urban India new opportunities like health insurance schemes, concessional train travel, holiday plans at luxury as well as budget hotels are gradually increasing. But the demand for 'geriatric products' in so far as pharmaceutical industry is concerned is growing rapidly.

Another way in which changing trends in social environment will affect business lies in the attitudes and expectations of your employees. It has become increasingly difficult to find goal congruence between the employees and the firm. The ever-increasing legislations and increased demands for workers put limitations on the strategic choices open to firms.

Here is a checklist to serve as a starting point to increase your awareness of how social changes in your firm's environment may affect its operations and options.

1. What changes in the composition of by age are likely to take place in the next five years? How are they likely to alter the demand for your products and services? What is the basis for your assumptions?
2. What changes do you envisage in the life styles and attitudes of your customers in the next five years? How are they likely to alter the demand for your products and services? What is the basis for your assumptions?
3. What changes do you foresee in age, life-styles, attitudes and expectations that are likely to affect the availability and quality of of your work force, whether they are production workers or office workers? And the supervisors and middle level managers? What is the basis for your assumptions?

Technological Environment

Technology is the most talked about subject today, from drawing rooms to the most powerful boardrooms. A major technological change is currently sweeping the world.

There are two major aspects of the technological environment that are of great concern to you. The ability of firms in your industry to innovate and find new methods of production that can substantially alter their costs and there by achieve the cost leadership.

This gives the innovative firm a definite competitive edge to nudge other firms out of the race. In the late 1990's, Cheminor drugs, a young bulk drug-manufacturing unit on a fast track offers a classic example of how technological superiority can achieve cost leadership.

Cheminor Drugs, a member of Dr. Reddy's Labs group has achieved phenomenal success with the production of ibuprofen by a different route and is mainly responsible for bringing down the price of ibuprofen below the international price level. They have repeated their success story a few years later with another drug, norfloxacin.

The second area of technological concern is the likely impact a new technology may have on your markets, products and services. For example, recent anti-ulcer agents such as cimetidine, ranitidine

and famotidine have carved out a sizable market for themselves in the in 1990's. This is evident from the fact that the top two prescription drugs in the world pharmaceutical market at that time were Zantac (ranitidine of Glaxo, now Glaxo SmithKline) and Tagamet (cimetidine of SmithKline Beecham, now GlaxoSmithKline). What is the impact of these anti-ulcer drugs on the antacid market? Has the market expanded? Have these new drugs taken a major share of the antacid market? Or have they taken a share of the gastro-intestinal surgery?

In India, the introduction of new broad-spectrum antibiotics has resulted in a shrinking market for narrow-spectrum injectable antibiotics and oral penicillin. The rate of product obsolescence is very high in pharmaceutical industry since it is technology-driven. Technological advancement is not restricted to new drug discovery alone. It can be a process improvement resulting in higher yield and lower costs, or the way in which the drugs are stored and delivered, or new production methods of delivering the drug at the site of action (New Drug Delivery Systems or NDDS) and making it more acceptable, patient-friendly as it improves patient adherence.

Close Watch

You have to be very alert and keep a close watch on the technological developments that are taking place in your industry, and how they are likely to affect your products and services. The key questions to be asked and answered are:

1. What are the major therapeutic groups where the maximum number of technological achievements occurred during the past five years? How did they affect your products and services?
2. Which companies had the maximum share of these technological achievements in the past five years? What was their R&D expenditure during this period? What have been their strengths and their vulnerable points?
3. What has been your development effort in new products area? What was the record of your innovation in the past five years? How many innovations were made? How many of them were successful?
4. Based on the above information, can you project what would be the likely developmental efforts of your firm and your major competitors within the next five years in the area of technological improvement, be it in the production area, packaging area,

distribution, storage, new drug delivery systems or new product introduction? How will they affect your products and services in terms of demand levels, market share and profitability?

5. What are your developmental plans and objectives for the next five years? What might be your competitors' plans?

The Ecological Environment

Ecology is perhaps the most rapidly changing aspect that affects the business environment. The increasing concern for maintaining the ecological balance is there for everyone to see. Not very long ago farmers could use any pesticide they chose, industrial wastes could be dumped or buried anywhere, pollution and its control was discussed rarely except as a matter of academic interest.

But not any longer! Pesticides and chemicals require extensive testing. Organic is the new mantra! Licenses for chemicals and pesticides are given only in locations that are specially earmarked outside the cities and towns. Industrial wastes require effluent treatment. One sees increasing protests and demonstrations against nuclear power plants. The ecological environment continues to change and the concern to maintain an ecological balance continues to grow.

The changing ecological environment can affect your business directly. The following key questions will expand your horizon about the many ways in which the changing ecological environment can create opportunities or pose threats to your business:

1. What processes and procedures in your manufacturing could be criticized as harmful to the environment?
2. If you were forced to change such procedures what would you do?
3. What about your suppliers? Do they use any processes and procedures that might be criticized as harmful to environment?
4. If your suppliers are forced to change such practices how would they affect the prices and availability of your raw materials and packaging materials?
5. Does your packaging create any environmental problem after the consumer uses it?
6. Are there any health hazards that might occur to you production

workers at the time of manufacture? How safe are your safety standards? Can you improve them?

7. Can you anticipate any other threats to your operation from the ecological environment? What are they? What can you do about them?

The Competitive Environment

Of all the external environments, in which the firm operates, it is the competitive environment that has the most immediate impact and is the easiest to understand. Apart from customers, your competitors are the most important determinants of your market share. Yet few companies try to analyze in-depth their competitors and understand them.

It is important that you prepare as complete a profile as possible of each of your major competitors. The important questions to ask are:

1. Company history of three major competitors for each of your major products.
2. Plant location.
3. Investment history of the last five years, plant expansion, new licensed capacities, public issues etc.
4. Financial history of the last five years like net sales, cost of sales, inventory, net income, total assets, operating expenses, gross margin, net margin, inventory turnover, profitability return on investment (ROI) etc.
5. Major products of competitors accounting for about 80 percent of their sales and their growth rate in the last five years.
6. Product quality of the competitors; what is the emphasis given by your competitors for product quality? How do they compare with your product quality standards on a ten-point scale?

When you are trying to appraise and analyze the external environment of your business, you should try to project the trends rather than predict the future. No one can predict the future accurately. History has demonstrated that amply. Therefore, do not be trapped in the number game. While it is important to be as accurate as possible regarding the historical data, any attempt at precision about the future

is likely to mislead you. What should concern you are general trends that you can make explicit in your planning. Your plans will be based on assumptions about the meaning of these trends. What is crucial about the whole business of projecting the needs is that you should be able to test the validity of these assumptions as the future comes to be the present.

The Ethical Environment

Pharmaceutical industry has discovered many drugs and therapies that have saved, prolonged, and improved countless lives of people over the years. However, the business exists to be profitable for itself and its shareholders in addition to existing over time. The pharmaceutical industry must constantly work to find a right balance of profitability without losing sight of its mission to discover new medicines to alleviate pain and disease of patients and to improve their health and quality of life.

Obviously, there is more to pharmaceutical marketing than marketing pharmaceuticals. Pharmaceutical marketing is significantly broader than marketing of pharmaceuticals because the justification or the reason for the existence of pharmaceutical marketing is the patient. That is why pharmaceutical marketing emphasizes that any article, service or idea needed to anticipate and remove gaps in patients' care to be included in the discussion of pharmaceutical marketing. This places a greater responsibility on pharmaceutical marketing.

From a marketing perspective, therefore, the ethical issues and influencers within the industry center on the various marketing communications by manufacturers of pharmaceuticals. Here are the ethical issues (Table 1.14).

Table 1.14 Key Ethical Issues in Pharmaceutical Industry

Area	Ethical Issues
A. Interactions with Health care professionals (HCPs)	Many healthcare professionals and their organizations have guidelines on how to interact with the pharmaceutical industry. The guidelines cover a number of areas such as: dealing with speakers, Support of CMEs, prohibition against entertainment and recreation.

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Area	Ethical Issues
B. Off-label Promotion	In all their communications with HCPs, pharmaceutical companies can only discuss approved indications. And yet, between January 2001 and 2009, pharmaceutical manufacturers in the US paid close to \$ 3-billion to settle suits involved in off-label promotion and marketing of certain medicines.
C. Publication Practices	<p>A. While the industry states that it conducts all its clinical trials in an ethical and rigorous manner, some research suggests that there is bias in industry sponsored studies that favors the companies sponsoring research.</p> <p>B. Research also suggests that there is not enough data transparency. And that industry publishes only clinical trials that are favorable to its product studied and hides the data that is not favorable to it.</p> <p>C. The ghost writing aspect of the publication practices is being scrutinized.</p>

The pharmaceutical industry must thus walk a fine line in promoting its products, and yet still being able to promote its products to provide the best of solutions for improving the health of patients. Companies that follow the industry and guidelines and market their products and services conforming to the best ethical standards are bound to do well in the market place. Media reports in recent times have brought to the fore the nexus between HCPs and pharmaceutical companies and a host of unethical practices. They have also tarnished the reputation of pharmaceutical industry that was earlier held in high esteem. The only route to restore the lost reputation of pharmaceutical industry is to walk the ethical path.

The pharmaceutical marketers should therefore monitor the ethical environment from outside and inside out continuously and constantly and make the necessary course correction. What is needed is an uncompromising attitude. The key questions to ask before taking any marketing decision are:

- A. Is this action of mine patient-centric?
- B. Will this action of mine lead to an improvement in patients' condition in any manner? Be it in terms of the cure, alleviation of suffering or quality of life.

Summary

The pharmaceutical industry in India has come of age from a mere US \$ 31 million in 1947 to a whopping US \$ 29.1 billion in 2017. This impressive growth is not without paradoxes. It was subjected to a stringent system of price controls on the finished products while the input costs were not controlled. This resulted in erosion of profits and profitability.

It is really commendable that the Indian pharmaceutical industry despite stringent price controls and a diminishing bottom line has achieved the coveted leadership in the international generics market. It is exporting bulk drugs and formulations even to the developed countries.

This big opportunity poses challenges as well as threats to the marketer who has to operate in the fiercely competitive Indian pharmaceutical market. He has to develop a thorough understanding and sensitivity to the rapidly changing environment. The marketing environment comprises:

1. The economic environment
2. The legal and regulatory environment
3. The social environment
4. The technological environment
5. The ecological environment
6. The competitive environment
7. The ethical environment

While no one can obviously predict the future, analyzing and appraising the environments that affect the business will equip and prepare the marketer to capitalize on the opportunities, meet the challenges and face the threats. One thing is for sure. Egalitarian or not, the market place is still very much a jungle where only the fittest survive.