PHARMA MARKETING IN INDIA

Prospects And Challenges

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ABSTRACT

In the recent years, Indian pharmaceutical market has exhibited 10% growth, as against 7% growth at the global level. However, there is a need to comply with WTO/IPR norms, and to bring in global standards by grabbing the huge potential of global pharmaceutical market. Indian firms have mostly English-speaking scientists and highly qualified and motivated young chemists, and have now faced stiff competition from Chinese firms which are producing world class pharmaceuticals at prices less than half as compared to the western countries. Further, mergers and acquisitions, liquidations and strategic alliances, and probably an attempt to create blockbuster brands for co-marketing of global pharmaceutical products will bring in newer opportunity for Indian talent pool of cheap skilled workers. Therefore, the Indian pharmaceutical companies must focus on their core competencies to produce world-class generics at highly competitive prices in order to capture the market share before Chinese grab it. The paper argues that it is possible only when Indian pharmaceutical companies seek to operate with highest efficiency and control the cost structure. This paper is an attempt to highlight the core competencies of successful Indian companies, and their capabilities to take leadership positions in global marketing of Pharmaceutical products, in the post-TRIPS era. For this, substantial investment in R & D is the need of the hour.

Introduction

In the recent years, Indian Pharmaceutical sector has witnessed a tough phase, hounded by VAT related concerns and brutal price erosion in the global generics market. Further, legal constraints including patent laws have gradually slowed down product launches in the country. There has been a pressing need for Indian companies to step-up R&D activities in a bid to get recognized as global discovery-led companies. With the changing dynamics, both in the domestic and the global markets, Indian Pharmaceutical companies are gearing-up to meet these challenges.

At present, for instance, about 20,000 pharmaceutical companies in India engage 5 million employees directly, with 2.5 million people getting indirect employment and million others engaged in the ancillary industries. The global market for contract manufacturing which is estimated at $48bn in 2007 is a lucrative sector, which Indian Pharmaceutical companies can grab very

easily due to competencies of Reverse Engineering and capacity to manufacture world-class products at a very competitive price.

With a very large market-size and population of over one billion, the Indian Pharmaceutical industry has very good future in the domestic market. While the per-capita spending on medicine is US$ 425 in Japan and $250 in US, the Indian per capita spending is only US$ 3. This strong demand potential indicates that the Indian Pharmaceutical industry could grab the opportunity of increasing its stake, despite competition from the global players. The Pharmaceutical industry could also boost its earnings through contract research and contract manufacturing. Further, with strong scientific base and cost competitiveness, the income of Indian Pharmaceutical industry from clinical trials would also exhibit significant rise in the near future. However, to witness such dream goals in future, this industry must adopt stringent quality norms. The Indian pharmaceutical industry has entered a new and challenging phase in the era of enforcing and recognizing product patents. The copycat era fostered domestic drug makers in the development of affordable medicines for people must come to an end. In the Post-TRIPS regime, manufacturing processes in Indian Pharmaceutical companies have been influenced mainly by copying drugs patented abroad.

Pharmaceutical Marketing in India:

If we go back in the history of the generic industry, we will find there have been troughs and valleys depending on patent expiry schedules. We are passing through one such phase. There has been a paradigm shift. Now, patent challenges have to be backed by an adequate flow from the generics pipelines. Only then does it make sense. But if a company is strategising only on patent challenges, it will run into a major handicap in the form of authorized generics.

The new patent law marks the end of protected era and signals the integration of India into global pharmaceutical market. India's dependence on world market is 33%. In the present situation Pharmaceutical industry must adapt itself to newly amended Patent Act. Only 13% to 14% of the products in the market are under patent. Not many products would come into market as the new amendment seeks to make copying of post-1995 patented drugs illegal. But, the impact of new regulations will not deter the Indian Pharmaceutical majors as they are already doing good business in the countries where these patent laws are strictly in force. Thus, patent has given the Indian Pharmaceutical sector a chance to try new methods of drug delivery and different combinations of molecules.

IDMA is of the view that the new patents law has some serious deficiencies and requires some urgent corrections. With the present provisions, MNCs will be in a better position than the domestic players and will enjoy undue advantage. The present policy will adversely affect the Indian consumers as well as domestic industry. The Royalty rates under compulsory licensing should be fixed at 4 per cent. Further, under the present Patents Law Compulsory License (CL) procedure U/S 87 is very lengthy and complicated. It is totally in favour of the Patent holder i.e. MNCs.

The domestic market can be broadly divided into two categories i.e. bulk drugs and formulations. Two key factors that have to be borne in mind are that the Indian Pharmaceutical market is highly fragmented due to the lack of a patent regime. Therefore, pricing power is limited and any player can duplicate a product in a very short span of time.

In drug formulations, there are two broad

categories i.e. lifestyle segment and traditional segment. Lifestyle segment comprises of drugs that are used to cure diseases that are linked to stress, urbanization and changing diet pattern and lifestyle of high-income level population. Major drugs in this segment are anti-diabetes drugs, cardiovascular system drugs, gentio-urinary and sex hormones drugs, CNS drugs, anti-depressants and psychiatry. These segments are not price sensitive and are less fragmented. The traditional segment, on the other hand, comprises of anti-infectives, pain management and anti-biotics. This segment is highly fragmented. Thus, if a company has higher exposure in the lifestyle segment, the growth prospects and margins of the company will be higher.

Generics are a bio-equivalent of a patented drug. Simply, if 'erythromycin' is coming out of patent, a company can launch the same erythromycin, but with a different composition (end effect however, is the same). Gradually, as the company grows, it shifts its focus onto developing a new drug delivery system for an existing drug and also challenges existing patented drugs by introducing their bio-equivalents. When a generics company challenges an existing patent, it is required to prove that the patent is not infringed or that the patent is invalid. He is thus required to prove that his drug is bio-equivalent to patented drug. If successful, the company gets a 180-day exclusivity period during which it has the sole right to sell the drug in the market. Consequently, the company enjoys very high margins during this period of exclusivity. However, the litigation expenses are likely to be very high in such a case.

Every year, a number of drugs come out of the patent regime. So, a company in India that does not have the R&D capabilities or funds to invest in R&D launches the generic version of the drug that is coming off patent. The advantage here is that the Indian company need not invest large sums in R&D. However, legalities are very complex and time consuming. When the company's research is at a very nascent stage, it concentrates on the sale of off-patent drugs.

Government policies have a major influence on the domestic Pharmaceutical sector. Due to the absence of a good health insurance policy, India has one of the lowest public health expenditure as a percentage of GDP. Moreover, even on the health infrastructure front, India has a long way to go as compared to other developing nations. R&D expenditure as a percentage of revenues is a very useful tool for evaluating the company's R&D thrust. As product patents come into effect, only companies with high R&D investment will survive. Thus, higher the ratio, higher will be the R&D focus of the company and the better placed will it be to face the uncertainties of the future. Of course, R&D has its inherent risks as well.

Keeping aside growth prospects, the Pharmaceutical sector has significantly high-risk profile due to the dynamism. Even erstwhile big names in the global Pharmaceutical industry like Upjohn, Burroughs, Knoll, SmithKline Pharma, Pharmacia and Hoechst, have found the going tough alone. Ultimately, they had to join hands with bigger players in a bid to survive. Some issues concerning Pharmaceutical marketing in India are as follows:

Lower-end of Value Chain:

Indian companies are cost competitive in manufacturing bulk drugs, which has made them an outsourcing destination for the global Pharmaceutical majors. But this is the lower end of the Pharmaceutical value chain and is basically a commodity making skill due to low entry barriers. Also, the Indian industry still lacks facilities and

resources to develop a molecule, conduct clinical trials and then launch the product. Indian companies will thus have to depend on their international peers to undertake the more expensive clinical trials and product launches.

Weakness in the Domestic Market

Fierce price competition has become the order of the day for the domestic Pharmaceutical industry, which has restricted the ability of the domestic Pharmaceutical market to grow in value terms. Due to its highly fragmented structure, the pricing power of players has been pruned. The Indian markets have traditionally been and continue to remain price sensitive and premium pricing of products is extremely difficult to maintain.

Challenging Generics Environment

Competition in the US and European generics market has intensified in the past year (2006-07) riding on the back of minimal product launches leading to brutal price erosion. While the product flow is set to increase in the coming couple of years, pricing pressure is expected to continue. Generic players also have to contend with a host of other challenges such as increased difficulty in securing Para IV wins, presence of authorized generics and making the right acquisition to acquire scale and effectively compete in the market.

Stumbling Blocks

Indian companies have been trying to enter US markets through Para IV filings. However, in recent times the industry has seen certain setbacks. This has reduced the companies' ability to generate strong cash flows to invest in ambitious R&D activities. This might lead to a delay in the R&D plans of domestic Pharmaceutical majors.

Impact of the Patent

The new patent regime brings in lot of promises for the industry in India, but it might not be good for the smaller players in the industry, as they will not be able to survive in the environment owing to scalability issues leading to consolidation of the industry. Also, the introduction of this law will gradually lead to a slowdown of new generic product launches from domestic Pharmaceutical majors in the Indian markets. At the same time, the law provides an attractive opportunity to multinational Pharmaceutical companies to step up product launches from their parent's product stable thereby providing competition to their domestic peers. This attribute continues to stay, despite the various moves to liberalize the industry. Drug Pricing Control Organization (DPCO) continues to exist.

Challenges before Indian Pharmaceutical Industry:

Indian Pharmaceutical sector has been marred by lack of product patent, which prevents global Pharmaceutical companies to introduce new drugs in the country and discourages innovation and drug discovery. But this has provided an upper hand to the Indian Pharmaceutical companies. Indian Pharmaceutical market is one of the least penetrated in the world. However, growth has been slow to come by. As a result, Indian majors are relying on exports for growth. To put things in to perspective, India accounts for almost 16% of the world population while the total size of industry is just 1% of the global Pharmaceutical industry.

Due to very low barriers to entry, Indian Pharmaceutical industry is highly fragmented with about 300 large manufacturing units and about 18,000 small units spread across the country. This makes Indian Pharmaceutical market increasingly competitive. The industry witnesses price competition, which reduces the growth of the industry in value term. To put things in perspective, in the year 2003,

the industry actually grew by 10.4% but due to price competition, the growth in value terms was 8.2%.

Moreover, there are certain concerns over the patent regime regarding its current structure. It might be possible that the new government may change certain provisions of the patent act formulated by the preceding government. Threats from other low cost countries like China and Israel exist. However, on the quality front, India is better placed in relation to China. So, differentiation in the contract manufacturing side may wane. The short-term threat for the Pharmaceutical industry is the uncertainty regarding the implementation of VAT. Though this is likely to have a negative impact in the short-term, the implications over the long-term are positive for the industry.

The value of the Indian pharmaceutical industry grew 11% in 2004 from 2003; with the top 10 Indian Pharmaceuticals accounting for 46% of the market, and R&D spend increasing by 36%. Compliance with international intellectual property protection and an increasing threat of foreign players moving into India are factors currently changing the dynamics of the market. Management is the most crucial aspect for any company's success. While this is true for every industry, it attains even more significance in the Pharmaceutical sector.

It is often said that the Pharmaceutical sector has no cyclical factor attached to it. Irrespective of whether the economy is in a downturn or in an upturn, the general belief is that demand for drugs is likely to grow steadily over the long-term. The Industry is a largely fragmented and highly competitive with a large number of players having interest in it.

Indian Pharmaceutical Industry in the Patent Regime:

In order to prevent "ever greening" of patents for pharmaceutical substances, provisions listing out exceptions to patentability (or what cannot be patented) have been suitably amended so as to remove all ambiguity as to the scope of patentability. This is very important in Indian context as it is very rich in traditional knowledge and heritage. The clear-cut instructions regarding what can not be patented would help public at large in a long run. The healing techniques of well established in ethnic system of medicines such as Ayurveda, Siddha and Unani system and formulations there in can not be patented.

Conditions for obtaining compulsory licence have been clarified in order to facilitate export of patented pharmaceutical products by Indian companies to countries that do not have adequate production capacities such as least developed countries. The compulsory licensing is an instrument that TRIPs allow by which governments can allow domestic manufacturers to manufacture patented products within three years of their introduction. The provision of this would be an opportunity for indigenous manufacturers to export the medicines to third world countries which can not manufacture their own drugs. There are many countries in Africa, Asia and South America which are in need of cheap drugs due to poor economic development in this area. It will be a boon for basic and formulation manufacturers as the market to this segment will definitely promotes opportunities.

Exemption of research and development from the ambit of patents, including experimental and educational purposes is noteworthy. High level research and education are the pillars of applied research. The education and research methodologies are the tools for developing science and technology. Barring this area from the patent, government wants to

ensure availability of trained manpower for sustained growth.

Over a period of time Indian drug companies will lose the opportunity to develop processes for patent protected drugs in the country. Indian drug companies might become dependant on MNCs for technology to produce new drugs. However, among existing drugs say about 10 per cent of the marketed drugs are likely to become expensive due to amendments made in new Patents Act. However, the existing 90 per cent of the old drugs will not be affected by this Act. While this is true, it must be understood that the rate of obsolescence of old drugs is extremely fast today. It was feared most that, technological dependence on MNCs will lead to establish their dominance over the Indian drug market. MNCs once again may start charging exorbitant prices for drugs in the Indian market. In product patent regime the drugs showing fastest growth would have been priced way beyond the capacity of the average consumer.

India, which has more than 70 US FDA-approved manufacturing plants, could become a production hub because of its cheap and skilled labour. "As of now pharmacy companies in India were thriving on reverse engineering but the rule of the game is likely to change and most firms belonging to the organized sector are fully geared to face the upcoming challenges. It must be noticed that outside the USA, *maximum number of US FDA-approved* plants are in India, which in itself is a testimony to the preparedness on the Indian industry. With patent protection, India could be ideal centre for activities of research and development and clinical studies. The contract research organizations of domestic and global are viewing as the hotbed for clinical research. The proficiency in English and skilled manpower, and availability of huge patient volunteers with this new amendment is going set phase for unprecedented opportunities for domestic manufacturers. Domestic manufacturers along with MNCs may also find it profitable to discover novel drugs for diseases of developing countries. The diseases like Malaria, Tuberculosis need to be addressed urgently. There seems to be stimulation in activities in this neglected field of diseases.

Indian Pharmaceutical Industry: Impact of TRIPS

Now, both the domestic and MNCs see the new environment with cautious optimism. India has introduced a new product patents regime, covering drugs, foods and chemicals. This is in compliance with the Trade-Related Intellectual Property Rights (TRIPs) agreement of the World Trade Organization (WTO). India has an enviable record of fully adhering to its international obligations. Moreover, strong patent laws are expected to encourage foreign investment in research and development projects and consequently benefit the Indian economy.

While TRIPs provide that the state can insist on issue of compulsory licenses to third-parties by the patentee, the conditions to qualify, as spelt out in the agreement, are rather stringent. It is permitted only under exceptional cases, affecting national interests, like in the case of Benefits to patents. TRIPs are expected to bring the following benefits to the Indian consumer and the country's economy:

- The consumer will get newer and better medicines. Medicines reduce other healthcare costs like hospital stay and surgical treatment.

- The economy will benefit through intensified R & D, foreign exchange earnings through out licensing of newly discovered molecules and more employment of researchers and research

supporting staff. Indian scientists will get protection for their intellectual property.

• Indian medicines will have better acceptability in well regulated markets of Europe and the U.S., leading to more exports.

• Domestic as well as foreign investment in pharmaceutical industry will increase substantially.

Indian Pharmaceutical Industry: Opportunities Ahead

Future of Indian pharmaceutical industry is bright. What is important is to make drugs available at affordable prices. We have the cheapest prices and will find a novel base. Also, reverse engineering is possible without infringing the patent. Knowledge that we have in abundance has to be utilized, as that is the big resource of growth.

India with a population of over a billion has a largely untapped Pharmaceutical market. In fact the penetration of modern medicine is less than 30% in India. To put things in perspective, per capita expenditure on health care in India is US$ 93 while the same for countries like Brazil is US$ 453 and Malaysia US$189.

The growth of middle class in the country has resulted in fast changing lifestyles in urban and to some extent rural centres. This opens up a huge market for lifestyle drugs, which has a very low contribution in the Indian markets. Indian manufacturers are one of the lowest cost producers of drugs in the world. With a scalable labour force, Indian manufactures can produce drugs at 40% to 50% of the cost to the rest of the world. In some cases, this cost is as low as 90%.

Indian pharmaceutical industry possesses excellent chemistry and process reengineering skills. This adds to the competitive advantage of the Indian companies. The strength in chemistry skill helps Indian companies and product markets to develop processes, which are cost effective. The Indian Pharmaceutical companies are marred by price regulation. Over a period of time, this regulation has reduced the pricing ability of companies. The NPPA (National Pharma Pricing Authority), which is the authority to decide the various pricing parameters, sets prices of different drugs, which leads to lower profitability for the companies. The companies, which are lowest cost producers, are at advantage while those who cannot produce have either to stop production or bear losses.

Cost Competitiveness - A new concept that is gaining momentum in the Pharmaceutical industry is contract research apart from contract manufacturing. Given the low cost high quality advantages, Indian companies are poised to benefit from contract research business on behalf of multinationals. As far as contract manufacturing is concerned, large global pharmaceutical companies are finding it profitable to outsource production. To cash in on these opportunities, many large production houses in the country are becoming US FDA compliant. To put things in perspective, excluding US, India currently has the highest number of sixty one US FDA approved plants.

Structural Changes - The penetration of health insurance is abysmally low in the country. The entry of private players would not only bring in quantum leap in the health insurance business but also increase capital inflows into this sector. It would also bring in the concept of managed healthcare in the country. This would finally lead to overall increase in per-capita usage of drugs.

Growth of the pharmaceutical markets in developing nations will clearly surpass that of the established markets. That situation

will provide one of the greatest opportunities currently available to the international pharmaceutical industry. Many developing countries have strongly growing economies; that factor constitutes a driving force in the reform and broadening of healthcare systems. Improvements in both the quality and reach of these healthcare provisions will drive the sales of branded and generic products. Private healthcare will undergo similar developments. Manufacturers of pharmaceuticals are currently working hard to address unmet healthcare needs in developing countries. By doing so, they are making better treatments available to millions of patients and improving the overall performance of their companies.

New Growth Opportunities - Despite the price war, the domestic Pharmaceutical industry continues to show decent growth rates, led by the chronic therapeutic (lifestyle) segment like anti-diabetic, cardiovascular and central nervous system. Higher awareness, exposure to newer therapies and aggressive introduction of new drugs at a reasonable price has been the key driver of growth in the chronic/ lifestyle segment. This trend is likely to continue going forward.

Increasing R&D Focus - One of the positive developments has been the shift towards product patent regime from 2005 onwards. This will lead to a structural change in the industry, which will encourage innovation and greater investment in R&D. Whereas, there would not be any impact in the short term, in longer term this will lead to strengthening and consolidation of the industry. Companies have been increasingly stepping up their R&D expenditure in a bid to be recognized as research and discovery oriented companies in the global arena from a long-term perspective. The migration into a product patent based regime is likely to transform industry fortunes in the long term.

The new patent product regime will bring with it new innovative drugs. This will increase the profitability of MNC Pharmaceutical companies and will force domestic Pharmaceutical companies to focus more on R&D. This migration could result in consolidation as well. Very small players may not be able to cope up with the challenging environment and may succumb to giants.

Large number of drugs going off-patent in Europe and in the US between 2005 and 2009 offers a big opportunity for the Indian companies to capture this market. Since generic drugs are commodities by nature, Indian producers have the competitive advantage, as they are the lowest cost producers of drugs in the world.

Opening up of health insurance sector and the expected growth in per capita income are key growth drivers from a long-term perspective. This leads to the expansion of healthcare industry of which Pharmaceutical industry is an integral part. India is increasing its R&D and biotechnology focus and taking advantage of the low R&D productivity of developed markets to gain partnerships with western players. These alliances enable the companies to gain expertise in discovery and development as well as maximizing revenues if and when products reach the market.

Excise on MRP from January 2005 has hit the small-scale drug units badly. Because of this change companies want to shift their manufacturing base to excise free zones. Many multinational companies have penetrated into India with an aim to market drugs and conduct clinical trails. Thus, Indian pharmaceutical research, manufacturing, and outsourcing have received an impetus, thereby, creating an image of a potential healthcare market and a land of opportunities in pharmaceuticals. The economic liberalization policies coming

to force in the 1990s and the strong emergence of private sector in the Indian economy has heightened the pace of development of the pharmaceutical industry and will continue to do so.

Conclusion:

With the product patent regime in place one may well ask what will happen to the formulations of molecules under patent currently being marketed in the country? In our opinion, the future of Indian pharmaceutical industry is bright. What is important is to enable companies to make drugs available at affordable prices. We have the cheapest prices and will certainly find a novel base. Also, reverse engineering is possible without infringing the patent. Knowledge, which we have in abundance, has to be utilized, as that is the big resource of growth. For this to happen, R & D must be given a substantial and sustained impetus.

Prices of only those drugs would go up that are patented newly and introduced for the first time in the Indian market. There is no such provision to check the prices of patented drugs. The government is contemplating to evolve a procedure to be followed to check prices of patented products.

There are fears expressed by large sections of consumer groups in India about a possible flare up in prices of essential drugs now. Prices of only those drugs would go up that are patented newly and introduced for the first time in the Indian market. There is no such provision to check the prices of patented drugs. The government is contemplating to evolve a procedure to be followed to check prices of patented products and we will support this move.

Being the lowest cost producer combined with FDA approved plants; Indian companies can become a global outsourcing hub for pharmaceutical products. Indian companies have recognized the opportunity presented by western Pharmaceutical in search of lower costs and higher profits, and are exploiting the low cost base and pool of highly skilled labour in their market to develop a thriving outsourcing industry, positioning India as a key provider of contract research and manufacturing services. At a growth rate of 9 per cent per year, the pharmaceutical industry in India is well set for rapid expansion. As a result of the expansion, the Indian pharmaceutical and healthcare market is undergoing a spurt of growth in its coverage, services, and spending in the public and private sectors. It is at this stage that we need to strengthen our core competency and invest in R & D activities so as to reap future benefits.

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