Journal of Business Excellence
ISSN: 0976-7711 & E-ISSN: 0976-772X, Volume 3, Issue 1, 2012, pp.-33-37.
Available online at http://www.bioinfopublication.org/jouarchive.php?opt=&jouid=BPJ0000255

PHARMACEUTICAL MARKETING STRATEGIES BASED ON CONSUMER WELFARE APPROACH IN THE NEW PATENT REGIME

TRIPATHI D.M.[1]*, TIWARI S.[1], TRIPATHI S.M.[2] AND YADAV P.K.[1]

[1]Department of Business Administration, M.J.P. Rohilkhand University, Bareilly-243006, UP, India.
[2]Department of Law, Tilkamazhi University, Bhagalpur-812001, Bihar, India.
*Corresponding Author: Email- durgeshmanitripathi@yahoo.com

Received: September 10, 2012; Accepted: November 01, 2012

Abstract- The recent change in the marketing strategy is work by multinational pharmaceutical Companies. It is now high time, rather than adaptive, development that is being carried out by leading Indian pharmaceutical companies. And, increasingly, other companies are finding themselves competing against, or working with, new innovation-research based companies. My study focuses on the processes and outcomes of Indian pharmaceutical companies in post patent regime. This article will present the changing production and marketing strategies in the new patent regime, keeping in view the consumer welfare.

Keywords- Pharmaceutical marketing, patent regime

Citation: Tripathi D.M., et al (2012) Pharmaceutical Marketing Strategies Based on Consumer Welfare Approach in the New Patent Regime. Journal of Business Excellence, ISSN: 0976-7711 & E-ISSN: 0976-772X, Volume 3, Issue 1, pp.-33-37.

Introduction

With the emerging and fast growing technology, internet information and in the face of intellectual property rights and TRIPS etc., today pharmaceutical industry is facing a challenging task and stiff competitions. In such competitive environment a pharmaceutical marketer has not only to stay a float, but also fight against the competitive tides. The pharmaceutical marketing environment is the most challenging one on the Indian industrial scene today. It is characterized by very intense competition with many companies, large medium and small, skirmishing for their own place in the market. The Indian pharmaceutical market is estimated as $ 8,790 million market. The growing population, demand for especially health care, and need for medicines to combat life style related diseases are leading to increase demand for quality pharmaceuticals and new medicines. In March 2005, the Indian Patent Third Amendment Bill established patent protection for pharmaceutical products in India [1].

Patent is designed to benefit both the creator and society as a whole, and it strikes a delicate balance to ensure that the needs of both are satisfied. It is assuming increasing importance worldwide due to their economic importance as well as its role in enhancing and cultivating the creative potential of the society. Patent makes it possible for the creator and innovators to establish themselves more readily, to penetrate new markets with a minimum of risk and to amortize the investments made in the research that lead to innovations in the first place. Patent protection in India has ushered a change in this highly fragmented industry. India has the largest number of US FDA approved manufacturing facilities out side the US. In 2003-04 Indian companies has filed highest number of DMF (Drug Master File) applications with the US FDA. Almost $ 60 billion worth of medicines are coming off patents in the next few years. India is poised to emerge as a significant player in the era of generics. The conductive environment with new schedule “M” for good manufacturing practices has prompted international Pharma companies to inter into alliances with domestic companies for generic drugs sourcing to be marketed in overseas markets. Indian companies like Ranbaxy, Dr. Reddy’s and Wockhard have begun international operations as well as acquisitions which will make a significant contribution to their turnover.

The growing demand along with product patent regulations has made the Indian market an attractive proposition for international companies. 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 potential healthcare market and land of opportunities in pharmaceuticals. The magnitude of effects due to introduction of patents depends largely on how much is the loss and gain in consumer welfare. In India, general income levels are low and consumers directly pay for the drugs (due to lack of penetration of medical insurance). Therefore, consumers are sensitive to changes in pharmaceutical market structure. Consequently, marketing plays vital role in consumer

welfare. The aim of marketing is to meet and satisfy needs and wants of target consumers. Marketing starts with consumers- what he wants to have and ends with the consumers- giving him what he wants [1].

In such competitive environment achieving excellence is no longer matter of choice, it is mandatory. So, it is necessary to develop and maintain a market information system to learn about consumer perception and attitude towards the companies, products, changing customer wants, new competitor initiatives and so on. Marketing research plays a vital role in generating this much-needed input of information. Thus, the Indian pharmaceutical industry with its rich scientific talent and research capacities, supported by an intellectual property protection regime and sound market structure, would reach exemplary heights.

Pharmaceutical Industry in Pre Patent Regime Era

The Indian pharmaceutical Industry is about 103 years old. Allopathic medicines were introduced several decades earlier mainly to provide medical relief to the Britishers. Indigenous production of these medicines was, however, started in 1901 with the establishment of 'Bengal Chemicals and Pharmaceutical Works'. In 1907, 'Alembic Chemical Works' was established at Baroda by T.K. Gaffar and Rafmitra B.D. Amine. But these units faced several problems like competition from overseas producers, lack of support from British Government and the prejudice against allopathic medicines at that time. At the down of independence, the pharmaceutical industry in India comprised the manufacturing units, which are merely engaged in the production of formulation based on imported bulk drugs. A few drugs, however, produced from late intermediates. The progress achieved in the production of fine chemicals and synthetic drugs was modest. Till 1970, only players in the field were Multinational Companies (MNC's) operating in India like Johnson & Johnson, Pfyzer, Roche, Sandoz, Ciba Geigy, E-Merck, Glaxo and others. Even then by 1970-71 the production of the bulk drugs was hardly INR. 50 Crores and of formulations INR. 250 Crores. The then Government of India decided to revamp the laws related to Patents so as to reduce the strong hold of MNC's and to provide an imetus to local industrial growth. Finally, considerable efforts went in formulating the Indian Patent Act 1970 [2]. This legislation implemented in 1972 made pharmaceutical product innovations, as well as those for food and agrochemicals, unpatentable in India thus greatly weakening IPR protection. It allowed innovations patented elsewhere to be freely copied and marketed in India. Therefore foreign firms did not find patenting in India worthwhile. This Act further restricted import of finished formulations, imposed high tariff rates and introduced strict price control regulations with the 1970 Drugs price Control Order. This led to a sea change in Pharmaceutical industry which grew leaps and bounds. The Indian Industry has a long way, being almost non existence before 1970 to a prominent provider of health products.

New Patent Regime and Growth of Indian Pharmaceutical Industry

The Indian Government issued the Patents (Amendment) Ordinance, 2004 on 26 December 2004, which has brought significant amendments in the Indian Patent law. The Ordinance was issued in the light of the completion of the extended timeline allowed to India conforming to obligations under the TRIPS agreement [1]. The Indian Parliament passed the Patents (Amendment) Bill, 2005 fulfill its obligations under the TRIPS Agreement and to achieve its goal of greater harmonization of patent laws across the globe. The Bill seeks to introduce product patents for food products, drugs and chemicals, to remove the transitional provision of exclusive marketing rights and rationalize and reduce the timeline for processing patent applications. '*IP rights are the rights given to people over the creations of their minds'* -WTO

Features of New Patent Regime

- Extension of product patent protection to all fields of technology
- Omission of Provisions pertaining to 'Exclusive Marketing Rights'
- Patents rights in respect of "Mailbox" Applications
- Redefinition of 'Inventive Step
- Omission of Software-Hardware combination provision
- Provisions for both "Pre-grant' and 'Post-grant' opposition
- Provisions for compulsory licence for export of patented pharmaceutical products
- Quantification of 'Reasonable period' with regard to compulsory licence
- Foreign filling permission for Indian resident
- Provisions for simplifying procedure and reducing the processing time for patent applications.

The Indian pharmaceutical industry today is among the front ranks of the country's science based industries with wide ranging capacities in the complex field of drug manufacture and technology [Table -1].

Table 1- Indian Pharmaceutical Industry: an Overview

The Indian Pharmaceutical industry has grown to INR. 40000 crores ($ 9 Billions) Currently	
Exports	INR. 17,0000 Crores
Compounded growth Rate	13.7 % per annum
Global ranking	By volume 4th, By volume 13th
Extremely Fragmented Industry	
Leading 250 companies market share	70%
Registered units	11,000
Large & Medium Scale units	300
Small Scale Units	10,000
Number of Drugs Under Price Control	74 (constitute about 37% of Formulations)
Number of Bulk Drugs & Formulations produced in India	More than 400 bulk drugs 7 about 60,000 formulations are produced in India meeting 95% of country's requirement
R & D Expenditure	4 to 6% of sale
Per Capita Drug Expenditure	INR. 250 Annually
Public Expending on Health	0.9% of GDP proposed to be increased to 2.3% of GDP
Future Market Size	INR. 1,12,500 crores ($ 25 billions) (Year 2010)
US FDA Approved Plants	Maximum US FDA approved plants (outside USA) are in
Number of drug Master Filings (DMF's)	India- approx. 80 Largest number of US DMF's 213 (38% of DFM's filled in first half of 2005 are from India)

It is estimated that with production over INR. 40,000.00 crore in financial year 2005, the Indian pharmaceutical industry rank 4th in terms of volume, but 14th in terms of value, contributing 8% to global sales volume and only 1% in value terms. The industry boasts of quality produces and many units are approved by regulatory authorities in the U.S. and Europe.

Factors Influencing Marketing Strategies in Post Patent Regime

India's pharmaceutical industry has the competitive advantage in improving its market share as prescription drugs worth more than US$ 65 billion have lost their patents in 2009-10 which enable India to become the regional hub in R&D, manufacturing and exporting activities. R&D departments are moving away from reverse-engineering in year of developing NDDS and discovery research.

Generic Market

The Indian generic drugs manufacturing industry is strong enough despite pricing pressure exerted on it from the generic markets of US and Europe. It represents a major growth portion of pharmaceutical. The Indian generic medicine industry has a competitive advantage due to relatively cheaper generics medicines and the opening of the generic markets in USA and Europe for the Indian firms. The generic margin for the firms is relatively low, although some of the Indian firms have very high profitability, with Dr. Reddy reporting gross margin of 52 percent in its 2002 Annual Report. It is predicted that an Indian company will be in the top largest generic companies in recent coming years.

Research and Development

A new drug takes 12 to 15 years with more than $88 million to be brought to market. In India, the current Research and Development investment is estimated at $100 to 150 million annually [Table-2], [Table-3]. It is relatively small compared to the global R&D spend of $60 billions.

Table 2- Initiatives Post-Patent Ordinance FDA and Approvals for Indian Companies

Year	Number
2002	21
2003	26
2004	25
2005	52
2006	74
2007	127
2008	134
2009	50

Table 3- R&D Expenditure (2008 to 2010)

Company	2008-9 [INR Crore]	2009-10 [INR Crore]	% Change
Ranbaxy	471.38	494.38	4.66%
Orchid Chemicals	52.39	54.46	3.80%
Wochardt	110.46	119.87	7.85%
Lupen	266.91	411.91	35.20%
Dr. Reddy's	421.2	389.7	-8.08%
Glenmark	61.9	51.85	-19.38%

Ranbaxy Laboratories a subsidiary of Daiichi Sankyo Co. of Japan remained the top R&D spender in absolute terms during 2009-10 at INR. 494.38 crores as compared to INR. 471.38 crores in the previous year. Ranbaxy's R&D spends as compared to stand alone net sales worked out to 10.3% as against 10.5% in the previous year. Orchid Chemicals managed to maintain the R&D expenditure at INR. 54.46 crores but this worked out 4.33% of its turnover during 2009-10 as against INR. 4.53% in the last year. The debt ridden Wockhardt stepped its R&D expenditure by 8.5% to INR. 119.87 crore from INR. 110.46 crore in the previous year. Lupen's R&D spending increased by 54.3% in 2009-10 to INR. 411.91 crore from INR. 266.91 crore in the previous year. The Research Park at Pune is focusing on Advance Drug Delivery System (ADDS) Noval Drug Discovery & Development (NDDD) and Biotechnology Research. The ADDS programme emerged as a key growth driver and area of strategic focus within the overall R&D programme.

Dr. Reddy's Labs' R&D spending declined by 7.5 percent to 389.70 crore from INR. 421.20 crore in the previous year. This worked out to 8.8 percent of its total turnover as against 10.04 percent in last year. The R&D expenditure of Glenmark Pharmaceutical declined by 16.2 percent to INR. 51.85 crore from INR. 61.90 crore in the previous year[Table-4]. However, its products pipeline is progressing well with seven molecules in clinics, of which two are ready for phase III trail.

Table 4- Development of New Medicines by Indian Firms (2008-09)

Company	No. of Molecules in Pipeline	Phase I	Phase II
Dr. Reddy's Lab	9	2	3
Ranbaxy	10		2
Glenmark	6	2	2
Nicolas Piramal	6		3
Wockhardt	5	2	1
Zydus Cadila	4	2	1

Contract Research and Manufacturing Services (CRAMS) & Contract Research Opportunity (CRO)

India, with its inherent competitive advantages and cost-effective manufacturing capabilities, has now become one of the most preferred destinations for Contract Research and Manufacturing Services (CRAMS) as the cost of manufacturing in India is 40 to 50 percent lower than in the developed countries. India holds huge potential to tap the $20 billion CRAMS business, which has expected to reach $31 billion by 2010. Pharmaceutical multinationals are also exploiting India's competencies in the field of information technology and its strong and low cost IT skill sets; by setting up centers for their global clinical data management functions in India. At present, a majority of clinical trials conducted in India are for Phase-II and Phase-III. If the government is allow Phase-I clinical trials for the drugs discovered abroad then it will enable the Indian CRAMS industry to provide a wide range of drug discovery services. Contract research also offers significant opportunity to the Indian pharmaceutical industry which is becoming a global R&D hot-spot for innovator pharmaceutical companies. The global contract research opportunity was $14 billion in 2006 has expected to reach $24 billion by 2010.

Mergers and Acquisitions in Indian Pharmaceutical Sector

Mergers and Acquisitions have become permanent business strategies in the Indian corporate sector in the post liberalization era. There has been a substantial increase in the number of M&A when compared with that during period of 1975-1990 [Table-5] and the

increase is quite substantial after the mid 1990's. However, the pace retarded during 2005-2009 due to global economic slowdown. A number of companies that have entered into merger and acquisition agreements in the context of the global market scenario these companies would be selling off the non-core business divisions like Over-the-Counter.

The lack of research and development (R&D) productivity, expiring patents, generic competition and high profile product recalls are driving the mergers and acquisition (M&A) activity in the sector. The key feature of M&A activity in Asia-Pacific has been consolidation of indigenous drug manufacturers, particularly in China and India. The number of mergers and acquisitions in the past months shows that the Indian pharmaceutical industry is all set to take on the global markets. Nicholas Piramal acquired 17 per cent in Biosyntech, a Canadian pharmaceutical packaging company in July 2005. Similarly, in June 2005, Torrent acquired Heumann pharmaceutical, a generic drug company that was earlier a part of Pfizer. Matrix's acquisition of the Belgian firm Docpharma was the largest acquisition deal. Sun Pharmaceutical Industries has announced its plan for acquisitions in the US.

Table 5- Trends in M & A's In the Indian Corporate Sector

Year	Mergers	Acquisitions	Total
1975 - 90	425	117	542
1990 - 00	661	407	1068
1990 - 95	236	91	327
1995 - 00	425	316	741
2000 - 05	993	2332	3325
2005 - 09	774	2199	2973

Collaboration

The rising global competition and the resulting downsizing has intensified the necessity for collaboration arrangements among pharma firms. Some foreign companies having patent rights try to tap Indian market and look for tie up with Indian pharma companies for marketing and distribution know how and expertise.

Drugs Prices in India

India was regarded as a supplier of low cost generic version of patented drugs to countries, which do not have sufficient manufacturing capacity and to some low income and least developed countries in Africa. If the government does not establish measures to bring prices down, the cost of new drugs remains very high, because patents allows monopoly power and prevents competition. Although least-developed countries are not obliged to grant patents on pharmaceuticals until 2016, these countries do not have the technical and financial capacity, nor the economies of scale to produce generic medicines. TRIPS implementation in India and other manufacturing countries will eventually cut the lifeline of affordable drugs unless safeguard measures are implemented to prevent this. TRIPS agreement does not specify or enforce anything regarding the prices of drugs and national governments are free to enact the measure within the ambit of TRIPS provisions to curb the increase in prices of drugs. In India, the stringency of the price control actually places on patented pharmaceuticals is the outcome of a complex bargaining prices between the Government and the industry. The granting of product patent rights to inventors, with limited scope for compulsory licensing, will strengthen the hands of firms in the negotiation.

Factors Influencing Consumer Welfare in New Patent Regime

Indian pharmaceutical sector has witnessed a decline in the extent of consumer welfare in majority of industries in the post liberalization era. There are variety of factors that influence the consumer welfare in the new patent regime.

A concentrated market does not necessarily result in greater loss of consumer welfare. This is because the Indian Government regulates the price in a concentrated market by setting the ceiling for the interest of the consumer. Merger & Acquisitions do not necessarily result in any significant change in loss of consumer welfare due to weak association between M&A and market concentration. Exports, Imports Advertising and technology are important with respect to consumer welfare. While greater imports strengthens the market presence of a firm vis a vis the rivals advertising restricts market competition through product differentiation and image advantage. In either case the consumer suffers.

Higher exports and better technology benefits the consumer in the form of greater efficiency and competitiveness of the firms and lower prices and more varieties of products. These are policy driven strategies hence these related policies have very important part in protecting the consumer's interest in the emerging markets.

Thus we observe loss of consumer welfare is more in industries with higher import intensity, greater efforts towards advertising and rising better financial performance. It is less in industries with larger penetration in the export market and greater technology efforts by the firm.

Conclusion

There can be various ways through which a Pharma organization can achieve success in the market, which revolves specifically around three parties or more; the triangular linkages or the relationship between these three parties (company, customers and competitors) In the medium to long run, the domestic pharmaceutical market will be largely driven by the increasing prevalence of chronic segment. The domestic industry is principally being driven by the chronic segment which has grown by 17.8% in recent year. Against the backdrop up- take of acute segments has been slow and has grown by 10.1% only. The basis of success in any competitive context can be, at the most, elemental level commercial success; and commercial success can be derived either from a cost advantage or a value advantage or ideally from a combination of both. In other words, the organization with Competitive Advantage tends to be the cost leader in the industry or a seller of most differentiated products amongst all the players. The role of supply chain is very prominent in both the phases (in acute as well as in chronic). In any pharmaceutical industry; when a company changes its concentration from "Acute" to "Chronic" therapy market it depend on competitiveness of supply chain and by understanding the customers' delivery requirements. The company must tailor its supply chain offerings to meet the needs of each of the market segment it serves. For example, Dabur Pharma has started launching of its products which were G.P. (Acute Therapy) oriented latter it enter in to specialists oriented (Chronic Therapy) products.

In respect of consumer welfare the Indian companies will have to reach out the end consumer is a variety of ways by setting up health clinics, hospitals, medical shops etc. This will help the com-

panies to increase consumer awareness for their products and less chances of substitution at chemist level. The rural Indians have to be tapped by pharma companies where only 20 percent of sales is accounted by pharma firms. The pharma companies should create stalls with doctors, develop vans as traveling/ dispensing pharmacies create contractual sales force region vise, tie up with FMCG companies to access their distribution, develop an efficient wholesaler system, and collaborate within the industry for better distribution. These attempts could provide a key for success of the Indian players against MNC's.

The Indian Government needs to actively participate and create a road map for Indian pharmaceutical industry to realize its full potential and to become globally competitive. Government needs to provide regularly protection that address global challenges India as an emerging integrated global pharma hub Indian, Government should give financial incentives and provide infrastructure for talent, innovations and research.

Thus, based on above ways, Indian pharma companies can effectively leverage on the opportunities available and continue to be one of the leading pharmaceutical industries in the world.

References

[1] Kotlar P. (1998) *Managing Marketing Information and Measuring Market Demand*, New Delhi, 9th Ed., 108-126.

[2] Reddy G.B. (2001) *Intellectual Property Rights & The Law*, 2nd Ed., 45.

[3] Jane Williams (2004) *Insider's Guide to the World of Pharmaceutical Sales*, 7th Ed.

[4] Pavan Choudary (1997) *The Rx Factor: Strategic Creativity in Pharmaceutical Marketing*.

[5] Mickey C. Smith, Kolassa E.M., Greg Perkins, Bruce R. Siecker (2001) *Pharmaceutical Marketing: Principles, Environment and Practice*.

[6] Kumar G.N.G. (2008) *Journal of Intellectual Property Rights*, 13.

[7] Jean O.L. (1997) *The Introduction of Pharmaceutical Product Patent in India*, Yale University & NBER.

[8] Chandran S., Roy A., Jain L. (2005) *Journal of Intellectual Property Rights*, 10, 269-280.

[9] Mishra P., Kumar V.K. (2011) *World Academy of Science, Engineering and Technology,* 56.