Competition Issues in the Generic Pharmaceuticals Industry in India

by

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1. Introduction

The pharmaceutical industry of India has matured over the years into a major producer of bulk drugs, rated among the top five in the world. The industry is largely concentrated in the production of 'generics' on account of the Process Patent Law introduced in the seventies (repealed under the recent TRIPS Agreement). India has since been able to establish technological capability for manufacture and supplying of generic drugs. This 'generics capability' of India has attracted worldwide attention. A noticeable surge in mergers and acquisitions with either a foreign company seeking a stake in an Indian counterpart or vice versa reflects the attractiveness of what has been called as the 'platform of capabilities'[1]. Indian companies seek to expand and consolidate their platform of capabilities in their endeavor to either develop indigenous branded generics or to acquire established branded generics. Today the Indian pharmaceutical industry has become a prominent provider of healthcare. It meets 95% of the country's medical needs and constitutes about 1.3% of the world market in value terms and 8% in volume terms represented by 250 large pharmaceutical manufacturers (5 of these are in the public sector) and about 8000 small scale units. The generics pharmaceuticals sector in India have come of age, their future sustainable growth depends on ensuring competitive markets and the Competition Commission is sensitive to the differing perspectives that are inevitable to an industry so critical to life itself.

2. Brief sketch of industry pharmaceuticals

The Indian Pharmaceutical Industry is among top five producers of bulk drugs in the world. Pharmaceuticals market can be roughly classified into Bulk drugs (20% of the market) registering growth rates of 20% and formulations (80% of the market) with an annual growth rate of 15%.

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* Member Competition Commission of India. The views expressed are personal and not to be taken as the views of the Commission. Any errors or omissions are entirely of the author.

[1] Chris Viehbacher, CEO. Sanofi-Aventis, *Business World*., September 2009.

There are about 8174 bulk drug manufacturing units and 2389 formulations units spread across the country. Pharmaceutical Companies Operating in India is a pool representing about 250 large Pharmaceuticals manufacturers and suppliers and about 8000 Small Scale Pharmaceutical & Drug Units including 5 Central Public Sector Units. At the time of independence, the bulk drug industry in India was in the infancy stage. Most of the bulk drugs and formulations were imported. Since then, the Indian pharmaceuticals industry has evolved through the opportunities arising within the regulated environment. The Indian Patents Act (1970) and establishment of large public sector companies for the manufacture of bulk drugs enabled the development of the pharmaceuticals industry in India.

The Indian pharmaceutical industry from being a pure reverse engineering industry focused on the domestic market, the industry is becoming research driven, export oriented and globally becoming competitive. The industry is dependent on its presence in the therapeutic segment and new categories, viz. cardiovascular, central nervous system and anti diabetic are expanding at double digit growth rates.

The generic drug companies in India have broad technological and diversified market capabilities. As more and more patents expire, the generic portion of the pharmaceutical market is expected to continue to have increased sales. Indian companies are attempting to tap the generic drug markets of the developed countries. The technological capability for manufacturing and supplying generic drugs of these companies make them major players in the international generics market. With the WTO commitment in Jan 1, 2005, to recognize foreign product patents outsourcing in the fields of R&D, contract manufacturing and co-marketing alliances have been identified by industry federations[2] as an opportunity for Indian companies. India has the best chemistry skills and low cost advantages in research and manufacturing and skilled manpower, which will attract foreign investors, apartment from encouraging basic research and drug discovery.

[2] Report of Federation of Indian Chambers of Commerce & Industries (FICCI) "Competitiveness of the Indian pharmaceutical industries in the new Product Patent Regime" in India., March 2005.

3. Branded Competition v/s Generic Competition

It is interesting to observe the responses of a matured generics player to competition, where large numbers of patents are expected to expire in a few years time. Few cases reported by media and newspapers, given below, provide glimpses of how Indian companies have taken legal measures to refute claims of multinational drug majors for extension of their patents.

a. A case that attracted a lot of attention in India is that of the Swiss drug company Novartis. Novartis had challenged Section 3(d) [3] of the Indian Patents Act claiming immunity for their drug Gleevic , a major drug for leukemia on the pleas that the new Gleevic was a major improvement over a older version whose patent was over. This was disputed by Indian companies such as Natco Pharmaceuticals. The plea of Novartis was rejected consequently enabling manufacture by Indian generic companies. Cost estimates of the new generic drug place it at one tenth the price of Gleevic.
b. In a similar case the Delhi Court rejected the petition of Bayer Healthcare, a German drug major from preventing the Drug Controller General of India giving marketing approval to Indian company Cipla for the generic version of the cancer drug Nexavar. The ruling however had a caveat namely, that if the Indian drug company is found guilty of patent infringement damages will have to be compensated by payment to Bayers.
c. Cipla in another case won the right to manufacture and market the generic version of the anti-cancer drug Tarceva originally patented by the Swiss pharma company Hoffman La Roche both in Delhi Court and the Supreme Court.[4]
d. Recently, Aurobindo Pharma an Indian drug pharma received USFDA approval for Risperidone Oral Solution a drug used in the treatment of mental and emotional problems. Indian companies are becoming increasingly active in the

[3] Section 3(d) of the Indian Patent Act forbids the patenting of derivative forms of known substances unless they are substantially more effective than the known substance. See Jayati Ghosh in her regular column 'Economic Currents'., *Deccan Chronicle.,* and also *Economic Times*, 29 August, 2009.

[4] Reported in *Financial Express*., 5th September,2009 and *Economic Times*.,19th August, 2009. The price difference for example, in the case of Cipla v/s Roche, Roche sells Tarceva for Rs.4500 per tablet while Cipla's generic is sold at Rs.1500 per tablet.

US market. In the first quarter of 2009 Indian companies had achieved 50 ANDA approvals.[5]

The European Commission investigation into the case of 'patent pooling' a commonly used tactics for prolonging the life of a patent has attracted a lot of attention in India. EU is probing into the anti-trust violations indulged by Lupin, Matrix Laboratories and Unichem Laboratories for 'knowingly delaying' the generic launch of a cardiovascular drug, Perinaopril by teaming with the innovator of the drug, Laboratories Servier.

4. History of Regulation in Pharmaceuticals

In this section we shall briefly outline the regulatory framework. The regulatory framework operates at two levels: i) licensing and ii) pricing. Licensing entails the need for manufacturers to get approval from Drug Regulatory Commissions at state-level. The Drugs and Cosmetics Act, 1940, governs the import, manufacture, distribution and sale of drugs, in India. The Drug Controller General of India (DCGI), an authority established under the Drugs and Cosmetics Act, 1940, oversees the conduct of clinical trials and is also responsible for the approval and registration of drugs, and issues manufacturing and marketing licenses for the same.

Essential drugs pricing is fixed by the Central Government. On a regular basis the list of drugs whose prices are controlled and the methodology of fixing prices is issued referred to as the Drug Price Control Order (DPCO). In the last few years only a few essential drug prices are regulated and the implementing authority as of now is the National Pharmaceutical Pricing Authority.

The Indian Patents Act (IPA), and the Drug Prices Control Order (DPCO) were both passed in 1970. Under the IPA, substances used in foods and pharmaceuticals could not be granted product patents. Only process patents were allowed for a period of five years from the date of the grant of patent, or seven years from the date of filing for patent, whichever was earlier. The introduction of the IPA provided a major thrust to growth of the Indian generics pharmaceuticals industry; and Indian companies, who through the

[5] See report on "The Indian Pharmaceutical Industry 2009"., Espicom Business Intelligence, May 2009

process of reverse engineering and synthesis, began to produce bulk drugs and formulations at lower costs.

The DPCO is an order issued by the Government, under Section 3 of the Essential Commodities Act, l955, empowering it to fix and regulate the prices of essential bulk drugs and their formulations. The order incorporates a list of bulk drugs whose prices are to be controlled, the procedure for fixation and revision of prices, the procedure for implementation, the procedure for recovery of dues, the penalties for contravention, and various other guidelines and directions. The order is subject to the guidelines of Drug Policy and supposedly aims to ensure equitable distribution, increased supply, and cheap availability of bulk drugs and played a vital role in directing the pharmaceutical industry's fortunes.

The first DPCO was issued in 1970, revised in 1979, 1987 and 1995. In its introductory form, DPCO was a direct control on the profitability of a pharmaceutical business, and only an indirect control on the prices of pharmaceuticals. It stipulated that a company's pre-tax profit from its pharma business should not exceed 15 per cent of its pharma sales (net of excise duty and sales tax). In case profits exceeded this sum, the surplus was deposited with the Government. So, a pharma company had the freedom to decide the prices of its products. Product-wise margins were also flexible, so long as the overall margin did not exceed the stipulated norm. Since individual product prices did not require approval from the Government, bureaucratic hurdles were low. DPCO (1970) effectively put a ceiling on prices of all mass-usage bulk drugs and their formulations. Its primary objective was to protect the interests of consumers, and ensure a restricted but reasonable return to producers. The order was a landmark regulation and has had several implications in shaping the Indian pharmaceuticals industry.

In 1974, the Government of India (Gol) appointed a committee under the chairmanship of Rajya Sabha MP, Mr. Jaisukhlal Hathi, to inquire into the conditions prevailing in the sphere of pharmaceuticals in the country. DPCO 1979 was loosely based on the recommendations of the Hathi Committee. The revised DPCO stipulated ceiling prices for controlled categories of bulk drugs and their formulations. The retail prices of

controlled formulations were decided by applying the concept of MAPE (Maximum Allowable Post- manufacturing Expenses).[6]

DPCO 1979 put 370 drugs under price control. These drugs were segregated into three categories, having different MAPEs. The most important drugs, including life-saving drugs were put in Category I, which had the least MAPE. Through this DPCO, around 80 per cent of the Indian pharma industry (in value terms) was brought under strict price control. However, 13 Transnational Corporations (TNCs) challenged the order and succeeded in obtaining a stay on the DPCO, 1979, from High Courts and ignored the prices fixed under this. Ultimately the Government of India had to appeal to the Supreme Court, which upheld the validity of its action and directed the Government to assess and recover the amounts.[7]

In 1984, the Government constituted another expert committee to look into the issue of drug pricing known as the Kelkar Committee. The Committee recommended the exclusion of a number of drugs from the purview of price control. Various suggestions were made for determining the criteria for inclusion and exclusion.

DPCO, 1987, was based on the Drug Policy of 1986, and the Kelkar Committee Report. In DPCO, 1987, the number of bulk drugs under price control was significantly reduced from 370 to 142. In addition, the categories of control were reduced to two, and higher MAPE was provided for each category of controlled drugs (75 per cent and 100 per cent respectively). However, around 75 per cent of the pharmaceutical industry was still under price control.

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[6] The pricing formula was retail price = (MC+CC+PM+PC) x (1+MAPE7100) + excise duty. MC was the material cost, including cost of bulk drugs/recipients; CC was the conversion cost as per the dosage form; PM was the cost of packing material suitable to dosage form; and PC was the packaging charge calculated in accordance with established costing procedures.

[7] In its judgment on April 10, 1987, the Supreme Court made a revealing observation. It discovered that Hoechst India Ltd. had fraudulently priced Earalgan Ketone, a non-essential drug. Hoechst applied for a price level of Rs. 3,500 per kg but was charging Rs.24,735.38 per kg. The Government, after analyzing the cost, fixed it as 1,810.20 per kg. Before the DPCO, Hoechst was charging a price of Rs. 24,735.38 per kg. But instead of reducing it to Rs. 1,810.20 per kg., or even Rs. 3,500 per kg., as requested of them, they continued to sell the drug for Rs. 24,735.38 per kg., under the protection of the High Court's stay order. The angered Supreme Court observed thus:

"We see that the price, of Rs. 24,735 per kg; at which the manufacturer was previously selling the drug, and at which he continues to market the drug to this day because of the quashing of the order fixing the price, by the high court; is so unconscionably high, even compared with the price claimed by itself, that it appears to justify the charge that some manufacturers do indulge in 'profiteering".

In September 1994, the New Drug Policy was announced. The New Drug Policy liberalized the criteria for selecting bulk drugs, or formulations, for price control. In addition, industrial licensing was abolished for all bulk drugs. All hindrances to capacity expansions were removed, and it was expected that, as a result, supply would rise, resulting in higher competitive pressures. Foreign investment up to 51 per cent was also permitted in the case of all bulk drugs, their intermediates and formulations. FDI above 51 per cent could also be considered on a case-to-case basis. Nevertheless, five bulk drugs; Vitamin B1, Vitamin B2, Folic Acid, Tetracycline and Oxy-tetracycline were reserved for the public sector till 1998.

The latest Drug Price Control Order was passed in 1995. The basic structure of this DPCO is the same as that of the earlier orders, except that a uniform MAPE of 100 per cent was granted to all controlled formulations. Nevertheless, the span of price control, under DPCO 1995, was liberalized considerably from 142 drugs to just 76. It was under the New Drug Policy, National Pharmaceutical Pricing Authority (NPPA**)** was appointed to implement and enforce the provisions of the Drugs (Prices Control) Order 1995 in accordance with the powers delegated to it.

Thus, the objective of the Government was to decontrol in order to induce increased competition and to make essential drugs affordable to the weaker sections of society.

5. Competition in the domestic market: Generics and the healthcare system:

How does the 'generic capability' of Indian companies emerging as major players in the world market affect competition in the domestic market? The domestic market is very competitive with a large number of players and is characterized by several market segments. There are pure generics; branded generics, formulations, with varying degrees of combinations and permutations among large players and small players. Surprisingly despite the comparative advantage in generics the Indian market remains largely untapped with one estimate on penetration of modern medicine placing it as less than 30%. [8] This applies to the healthcare segment. The basis for competition exists. While the objective of the government to decontrol in order to increase competition the concern of the Commission is on ensuring competition and on this aspect it is worthwhile

[8] "Indian Pharma Industry: SWOT Analysis: internet report., June ,2009

to glimpse briefly at the the dynamics of the Indian pharmaceutical sector and also the health care segment.

While the number of drugs decontrolled has increased, the maturing of the pharmaceutical industry can be seen in the wide range of drugs ranging from pure generics to branded generics enabling the consumer to exercise choice. Studies have shown that a generic controlled by DPCO required to be sold at an MRP of Rs. 7/- per strip can be marketed separately as a branded drug at Rs. 15/- per strip i.e. at double the price, often on account of variations in the chemical combinations of the branded generic as compared to the generic drug. This suggests developing universal classification systems, but there are limitations to such universality.

The choice of patients to either buy generics or branded drugs to some extent may be influenced by whether they seek to avail of the public health system or go to a private hospital and within the two systems there are again several again options. Access to drugs and healthcare is an important dimension of ensuring competition between branded generics and generics. Similarly, information available in the public domain on common drugs can also have a contributing role towards competition.

While there is range of choice open to consumers, the exercise of choice is determined by several factors but the critical factor is on the availability of information. In brief, competition as always depends on ensuring smooth and free flow of information. Towards this end the suggestions are:

(a) Strengthening the existing regulatory system especially for enabling more detailed and universal classification of drugs and chemicals between branded generic and generic

(b) Strengthening the public information system where simple drugs are known to consumers

(c) Strengthening the public procurement process of drugs by public health system.