Seventh United Nations Conference to review the UN Set on Competition Policy

Geneva, 6-10 July 2015

Roundtable on:

Role of Competition in the Pharmaceutical Sector and its Benefits for Consumers

Contribution
By

India

The views expressed are those of the author and do not necessarily reflect the views of UNCTAD

THE BENEFITS AND THE ROLE OF COMPETITION FOR CONSUMERS IN PHARMACEUTICAL INDUSTRY

I. INTRODUCTION

Health is a crucially important social and economic asset – a cornerstone for human development. Pharmaceutical products play an important role in healthcare along with well-trained and motivated health professionals. Pharmaceutical sector makes a valuable contribution in improving the public health by developing, producing, distributing and marketing the needed drugs or pharmaceutical products. A competitive market provides consumers access to good quality medicines at comparatively lower prices. Competition also forces companies to invest more in research and development (R&D) for developing better quality drugs and new drugs, which may contribute to improvement in quality of life of consumers.

Several characteristics of the pharmaceutical sector such as information asymmetry, lack of decision making by consumers, and low elasticity of demand have implications for the level of competition in these markets. Some of the issues like collusion between players at different levels in the pharmaceutical supply chain, exclusive supply and distribution agreements, patent related issues including abuse of market power, anti-competitive mergers etc. may adversely affect competition in the market.

India is one of the biggest emerging markets of pharmaceuticals and therefore, competition in this market is crucial for making quality drugs at affordable prices available to consumers. Application of competition law to the pharmaceutical industry plays an important role in dealing with the anti-competitive issues in the sector and maintaining competitive markets.

This paper provides a brief overview of pharmaceutical sector in India including the regulatory framework. Thereafter, enforcement as well as advocacy activities of the Competition Commission of India (CCI/ Commission) pertaining to the pharmaceutical sector are briefly discussed.

II. INDIAN PHARMACEUTICAL INDUSTRY

The Indian pharmaceutical sector is one of the fastest growing sectors of the economy. The entry of generic drugs in the market after the expiry of patented drugs is a major reason for drastic fall in prices of the medicines and has played an important role in improving accessibility of medicines in India.

The Indian pharmaceutical industry is one of the major contributors to the requirement for pharmaceutical products globally, and is a cheap source of

medicines to the developing world[1]. Indian Pharmaceutical Companies produce 'Bulk drugs' as well as 'Formulations'. Around 77 percent of the firms in the sector are engaged in the production of formulations and only 23 percent in bulk drugs[2].

Indian pharmaceutical industry broadly functions under a three tier structure. The large MNCs operating as originator drug companies and generic companies, along with the large Indian generic companies form the first tier. In the second tier, the medium and small scale industries are engaged in the production of branded generics and contract manufacturing related activities. In the third tier, most of the units in the small scale sector are engaged in production of generic-generic medicines.

In 2014, the top four firms in the sector accounted for 20 % market share in terms of revenue, whereas top 10 firms garnered 39 % market share[3]. However, presence of large number of small scale firms in the sector is an important feature of Indian pharmaceutical industry.

In view of the social and economic impact of public health and issue of safety of human lives, world over pharmaceutical sector is highly regulated for providing safe and quality drugs at affordable prices with India being no exception. The Indian pharmaceutical industry is regulated at two levels; licensing and pricing.

III. COMPETITION ENFORCEMENT BY CCI

The relevant legislation for enforcing competition in India is the Competition Act, 2002 (Act) under which the Commission has been established to promote and sustain competition in the markets. Like most modern competition laws, the Act prohibits anti- competitive agreements (section 3), abuse of dominant position (section 4); and regulates combinations (sections 5 and 6).

The Act also recognises the importance of IPRs including patents. While section 3 of the Act prohibits anti-competitive agreements, sub-section (5) of section 3 recognises the right of a person to restrain any infringement of the rights conferred upon him inter-alia under the Patents Act, 1970. The Act also enables such persons to impose reasonable conditions for protecting such rights.

A. Enforcement

The provisions of the Act relating to anti-competitive agreements and abuse of dominance came into force with effect from 20.05.2009 and those related to mergers

[1] Department of Pharmaceuticals, Annual Report (2013-14).
[2] www.dsir.gov.in/reports/isr1/**Pharmaceuticals**/7_3.pdf accessed June 1, 2015.
[3] IBEF's Sectoral Report on Pharmaceutical Sector (March 2015). http://www.ibef.org/download/Pharmaceuticals-March-2015.pdf .

and acquisitions from 01.06.2011. Since then, some of the important cases relating to pharmaceutical sector handled by CCI are briefly discussed below:

1. Anti-competitive practices in distribution of pharmaceuticals

Till date, the Competition Commission of India has dealt with several cases involving anti-competitive practices prevailing in the distribution chain of pharmaceutical sector and has found violation of section 3 of the Act by trade associations of chemists and druggists. *Varca Druggist & Chemist & Ors* v *Chemists and Druggist Association, Goa*[4] was the first case dealt by the Commission relating to pharma sector. In view of long entrenched practices and their grave impact on public health, apart from cases before the Commission initiated pursuant to filings, CCI has also initiated *suo moto* investigations and given widespread publicity to the penalization of such local associations.

The primary allegations in these cases generally related to:

i) **Restrictions on Manufacturers:** Pharmaceutical Companies were subjected to several restrictions in supplying their products to the markets:
   a. No Objection Certificate (NOC) had to be taken from the trade association before appointing stockists for distribution of drugs;
   b. Only members of the trade association could be appointed as stockists/distributors;
   c. More than the specified number of wholesalers in an area could not be appointed;
   d. The appointment of a third, fourth or fifth wholesaler was only allowed, if the other wholesalers had met certain revenue targets set by the association;
   e. Approval from association was necessary for introduction of drugs in the market after paying charges to the association for a service called the Product Information Service (PIS).

ii) **Restrictions on wholesalers/stockists:**
   a. Stockists could not sell products of a pharmaceutical company before obtaining NOC from the existing stockists of that pharmaceutical company operating in the area. Associations formulated guidelines for its members to obtain permission/NOC before becoming a stockist of a particular company;
   b. Associations fixed trade margins below which the stockists were not allowed to sell[5];
   c. The distributors/ retailors were also not allowed to give discounts to customers.

[4] Case No. MRTPC 127/2009/DGIR4/28.
[5] The trade margins for controlled drugs are regulated by the Central Government through Drug Price Control Order, 1995 (DPCO). Associations fixed trade margins for uncontrolled products.

iii) **Levy of fines:** Fines were levied by the associations on manufacturers as well as distributors/stockists found to be not complying with their guidelines.

iv) **Restrictions on bidding for public procurement**: Only authorized stockists were allowed to bid for supply of drugs to the government and the hospitals.

v) **Boycott:** All India level and state associations boycotted the drug manufacturers, who did not adhere to the restrictions imposed on them by issuing directions to players in the distribution chain. Similarly, the drug manufacturers were forced to stop supplies to the stockists, who disobeyed these directions.

The Commission in these cases held that the said practices of the associations were anti-competitive in nature and, therefore, ordered the respective associations to cease and desist from engaging in such practices and also file an undertaking to the effect that such practices had been discontinued. The Commission also imposed penalty on the concerned associations. In some of the cases, CCI also imposed penalty on individual office bearers of the associations. In *Santuka Associates Pvt. Ltd.* v *All India Organization of Chemists and Druggist Associations (AIOCD),* the national level umbrella organisation AIOCD was found to be in violation of the Competition Act and penalised.

A review of the above cases clearly highlights that such practices reduce both competition amongst suppliers and choices available to consumers. The cases discussed above essentially represent the first few steps taken by CCI towards restoration of competition in the distribution chain of medicines in the country.

2. BID RIGGING IN PUBLIC PROCUREMENT

Action against bid rigging in public procurement is a key tool of competition enforcement, especially in developing countries where government spending accounts for a high percentage of GDP. CCI too recently handled a case relating to bid rigging in public procurement in pharmaceutical sector, which is briefly discussed below:

BIO-MED PRIVATE LIMITED V UNION OF INDIA & OTHERS (CASE NO. 26 OF 2013): The case involves bid rigging by GlaxoSmithKline (GSK) Pharmaceuticals Limited and Sanofi, two major global pharma players, in a government tender for procurement of QMMV- an anti-meningitis vaccine. The case was filed by Bio-Med Private Limited and related specifically to the tender floated in 2011. It was alleged by Bio-Med that GSK and Sanofi had colluded and divided the market in contravention of the Act.

During the investigation, the Director General (DG) collected detailed information from the parties relating to their business models, decision-making policies etc. The

DG analysed the technical and the price bids submitted by GSK and Sanofi in the tenders and found a clear bidding pattern that indicated the existence of a cartel between them.

After considering the investigation report and hearing the parties, CCI held that the conduct of GSK and Sanofi demonstrated that they were acting pursuant to an anti-competitive agreement and held them guilty of contravention of the provisions of section 3(3)(d) read with section 3(1) of the Act. CCI levied a fine on both companies at the rate of 3% of their turnover amounting to INR 640 million approximately.

3. Merger Review

In recent years, world over (including in India), pharmaceutical industry has witnessed increased M&A activities. CCI has dealt with several cases of M&A in the sector, such as the acquisition of *Agila Specialties Pvt. Ltd*. by *Mylan Inc*, merger between *Sun Pharma* and *Ranbaxy* etc. All these pre-merger notifications involved companies engaged in manufacturing of pharmaceutical products and were approved by the Commission within a period of 30 days in phase I itself (except the Sun Pharma and Ranbaxy merger, discussed below) as it was observed that the parties had either limited presence in domestic market in India or there was insignificant overlap between the products offered by combining parties in India.

APPROVAL OF MERGER BETWEEN SUN PHARMA & RANBAXY LABORATORIES LIMITED: The Commission observed that both parties are primarily manufacturers of generic drugs, with a small number of licensed molecules. The Commission considered it appropriate to define the relevant product market at the molecule level (i.e. molecules based on the same active pharmaceutical ingredients (API)) in the said case. On the basis of the combined market share of the parties, incremental market share as a result of the proposed combination, market share of the competitors, number of significant players in the relevant markets etc. the Commission focussed its investigation on 49 relevant markets for formulations where the proposed merger was likely to have an appreciable adverse effect. In addition to these relevant markets, the Commission also investigated two pipeline products of Ranbaxy and the possibility of any vertical foreclosure in the market for APIs.

On the basis of its assessment, the Commission decided that the proposed combination is likely to result in appreciable adverse effect on the competition in the relevant markets for seven formulations in India. However, such adverse effects could be eliminated by suitable modifications. Accordingly, the Commission approved the proposed merger subject to the Parties inter-alia carrying out the divestiture of their products relating to these seven relevant markets for formulations.

NON-COMPETE CLAUSE: Another factor of concern in M&A is the non-compete clause, whereby two groups or companies formally agree not to compete in the relevant market. This may directly affect the present competition as well as future R&D in the

sector. The longer the period of non-compete clause, the greater may be the harm to the competition. In India, considering its adverse effect on consumers, a non-compete clause is not allowed in brownfield investment except in special circumstances. The issue of non-compete clauses in transactions relating to the pharmaceutical sector has also been deliberated by the Commission in some cases such as *Orchid Chemicals & Pharmaceuticals Limited* and *Hospira Healthcare India Private Limited*; *Agila India* and *Mylan* etc. In these cases, the Commission has held that:

i) *non-compete obligations, if deemed necessary to be incorporated, should be reasonable particularly in respect of:*

> *(a) the duration over which such restraint is enforceable; and*
>
> *(b) the business activities, geographical areas and person(s) subject to such restraint, so as to ensure that such obligations do not result in an appreciable adverse effect on competition.*

ii) The scope of the non-compete covenant should cover only those products, which are either being presently manufactured/sold or are under development, by the target enterprise.

B. Advocacy Measures

While enforcement is very crucial, there is a need for greater awareness among the market participants including not only the generic and innovator pharmaceutical companies but also the distributors, doctors, consumers and the regulatory agencies etc, about the importance of competition in the market. The Act mandates the Commission to take suitable measures for the promotion of competition advocacy, creating awareness and imparting training about competition issues.

Keeping in mind the importance of the pharmaceutical sector in the economy, the Commission supplements its enforcement action through rigorous advocacy measures. Accordingly, CCI takes various advocacy initiatives such as issuing public notices in the leading newspapers to sensitize the public at large about the anti-competitive practices prevalent in the sector and the remedies issued by CCI. Besides, the Commission continuously engages with the relevant governmental agencies to foster competition in the sector. Such initiatives have resulted into heightened awareness amongst the stakeholders leading to increased filings before the Commission. The sector continues to remain high on the priority agenda of the Commission and the Commission proactively endeavours to correct market distortions prevalent in the sector through a mix of enforcement and advocacy initiatives.

Annexure 1: List of Cases relating to druggist associations

NO.	CASE	ISSUES	PENALTY *(Indian Rupees)*
1.	Varca Druggist & Chemist & Ors. vs Chemists and Druggists Association, Goa	Mandatory membership, PIS approval and charges, issuance of NOC, restriction on appointment of distributors, setting of margins Local association involved	0.2 million
2.	Vedant Bio Sciences vs Chemists & Druggists Association of Baroda.	Mandatory membership, issuance of NOC, restriction on appointment of distributors, setting of margins Local association involved	0.053 million
3.	Santuka Associates Pvt. Ltd. vs All India Organization of Chemists and Druggists & Ors.	Issuance of NOC, PIS approval and charges, restriction on appointment of distributors, setting of margins, boycott of companies National association involved	4.74 million
4.	Sandhya Drug Agency vs Assam Drug Dealers Association & Ors.	PIS approval and charges, issuance of NOC, restriction on appointment of distributors, setting of margins, boycott of products National and Local association involved	0.56 million
5.	Peeveear Medical Agencies, Kerala vs All India Organization of Chemists and Druggists & Ors.	PIS approval and charges, issuance of NOC, restriction on appointment of distributors, setting of margins, boycott of products National and Local association involved	Penalty previously levied in similar cases
6.	Arora Medical Hall, Ferozepur vs Chemists & Druggists Association, Ferozepur & Ors.	Issuance of NOC, boycott of distributors Local association involved	5.54 million
7.	In Re: Bengal Chemist and Druggist Association And Reference Case filed by Director, Directorate of Drugs.	Non-allowance of discounts, setting of margins, enforcement of anti-competitive agreements, boycott of distributors Local association involved Reference received from public authority and *suo moto* case	183.85 million
8.	Collective boycott/refusal to deal by the Chemists & Druggists Association, Goa, M/s Glenmark Company and, M/s Wockhardt Ltd.	Non-compliance with the previous orders of the Commission, issuance of NOC, boycott of distributors. Local association involved *Suo moto* case	1.06 million
9.	Rohit Medical Store vs Macleods Pharmaceutical Limited & Ors.	Issuance of NOC, PIS charges Local association involved	0.29 million
10.	Bio- Med Pvt Ltd vs Union of India & Others	Cartelisation in bidding process	630 million

Annexure 2: List of combination cases

	CASE	YEAR	OUTCOME
1	Notice for Acquisition filed by G&K Baby Care Private Limited	2011	Approved
2	Notice for Acquisition filed by Orchid Chemicals & Pharmaceuticals Limited and Hospira Healthcare India Private Limited.	2012	Non-compete clause modified
3	Acquisition of the global nutrition business of Pfizer by Nestle	2012	Approved
4	Notice for Acquisition given by Mitsui & Co. Limited.	2012	Approved
5	Notice given by Mylan Inc.	2013	Non-compete clause modified
6	Notice given by Mylan Laboratories Ltd.	2013	Approved
7	Notice given by Anant Investments.	2013	Approved
8	Notice given by Novartis AG and GlaxoSmithKline plc	2014	Approved
9	Notice given by Wipro GE Healthcare Private Limited and GE India Technology Centre Private Limited.	2014	Approved
10	Notice given by Sun Pharmaceutical Industries Limited and Ranbaxy Laboratories Limited	2014	Approved with structural modifications
11	Notice given by Meiji Seika Pharma Co., Ltd.	2014	Approved
12	Notice given by Sanofi-Synthelabo (India) Limited	2014	Approved
13	Notice for acquisition given by Torrent Pharmaceuticals Limited and Elder Pharmaceuticals Limited.	2014	Non-compete clause modified
14	Notice given by Glenmark Generics Limited, Glenmark Access Limited and Glenmark Pharmaceuticals Limited.	2014	Approved
15	Notice given by New Moon B.V.	2014	Approved
16	Notice given by Beckman Coulter, Inc. and Beckman Coulter India Private Limited	2014	Approved
17	Notice given by Dunearn Investments (Mauritius) Pte. Ltd.	2014	Approved
18	Notice given by Strides Arcolab Limited and Shasun Pharmaceuticals Limited	2015	Approved
19	Notice given by Ordain Health Care Global Private Limited	2015	Approved
20	Notice given by Wipro GE Healthcare Private Limited, Mr. S. Ganeshprasad, Mr. Kiran Thadimarri & Mr. R. R. Balaji	2015	Approved