



COMPETITION ISSUES IN THE INDIAN PHARMACEUTICAL SECTOR



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Outline

- Key features of Indian Pharmaceutical Industry
- Regulatory Framework
- Recent Developments
- Competition Assessment of Pharmaceutical Cases



Key Features of Indian Pharma. Sector

- Regulations governing the sector are designed to
 - ✓ Promote research and innovation
 - ✓ Ensure safety of drugs
 - ✓ Control public and private expenditure
- One of the largest and most advanced pharmaceutical industries among the developing countries
- Characterised by information asymmetry and supplier induced demand whereby consumption decisions are taken by the prescribing physician and not directly by the consumers of the pharmaceutical products.

Key Features of Indian Pharma. Sector



- Apart from ultimate consumer i.e. patients, the demand function of drugs also depends on physicians, hospitals and pharmacists.
- The notion of consumer choice leading to price competition fails in the prescription drug market.
- Generics are an important source of competition to branded drugs and thus policies should target smooth introduction of generics.
- Among the highly regulated industries across the globe, yet often subject to criticism that the required degree of competition is missing from these markets

Regulatory Framework



- **Competition Act, 2002**
 - Provisions related to anti-competitive agreements and abuse of dominance came into force with effect from May 2009
 - Provisions related to mergers and acquisitions came into force with effect from June 2011
- **Framework for pricing by the Government**
 - Pricing of essential drugs is regulated by the Central Government through Implementation of National Pharmaceutical Pricing Policy, 2012 (NPPP) and the corresponding Drug Price Control Order 2013.
 - NPPP and the DPCO regulate prices of essential drugs by fixing a ceiling price on the basis of simple average of market prices.
 - Separate policy for pricing of patented drugs likely to be notified soon.

Regulatory Framework



IPR in Pharmaceutical Market

- Pharma sector ranks on top in terms of reliance on IPR protection and related litigation
- In absence of patent protection, 65% of pharma products would not have been introduced.
- Protection offered by patents may however be disproportionate to the cost of innovation when there is inadequate competition in R&D e.g. fresh patents for minor improvements in existing patented products.

Patent protection has both advantages and disadvantages

Advantage – Stimulating, Promoting and Rewarding Innovation

Disadvantages – Exclusive rights resulting in market power and its potential abuse

- Competition law and IPR protection are assumed to be on different sides of a continuum, but actually both intend to enhance market efficiency

Some Recent Developments



Pay for Delay Settlements

- ✓ Used by patented drug makers (Originators) to **extend the exclusivity period** of their patented drug in order to prevent the market entry of generic drug suppliers (Generics), on or before the expiry of their patents
- ✓ Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a '**reverse payment**' settlement agreement
- ✓ However, they are anti-competitive in nature as they **eliminate the potential competition** and provide for sharing the resulting profits

Some Recent Developments



Ever-Greening of Patents

- Ever-Greening is an “Abuse of Patent System” and considered to be anti-competitive in nature by enhancing the term of monopoly of patent holder and delaying introduction of generics in the market
- Supreme Court in April, 2013 in the case of Novartis Vs. UOI & Others
 - ✓ upheld the constitutional validity of Section 3(d) of Patents Act, 2005 and laid down “enhanced therapeutic efficacy” as a test for grant of patents; and
 - ✓ accordingly, refused to grant a patent to Novartis for its cancer drug “Glivec” as it does not qualify the test of “Invention” as laid down in Section 2 of the said Act
 - ✓ Court further held that “Glivec” is based on a known substance and is just an “Incremental Invention”
- Thus, Novartis judgment reaffirm S. 3(d) as a “Second tier of qualifying standards” for patentability and in a way tries to protect “competition from generics” for securing consumer interests
- **Supreme Court order seeks to leave the door open for true and genuine inventions but, at the same time, aims to check any attempt at repetitive patenting or extension of the patent term on spurious grounds.**

Some Recent Developments



Compulsory Licensing (CL)

- ✓ Legal instrument designed to force intellectual property owners to license out their statutorily granted right to interested third parties capable of manufacturing the patented product at cheaper prices
- ✓ In March 2012 the Indian Patents Office granted its first compulsory license, for the manufacture and sale of Bayer's patented drug Nexavar to Natco Pharma Limited
- ✓ Under the Patents Act, CL may be granted after three years of grant of patent on any of the these grounds – “Un-affordability”, “Non-Accessibility” and “Patent invention not worked in India”
- ✓ Requires careful balancing between need to encourage innovation vs. goal of promoting and fostering competition

Provisions in the Act



- Compulsory Licensing/Divestiture
 - ✓ Under the Competition Act, an enterprise is guilty of abusing its dominant position if, *inter-alia*, it imposes unfair prices, limits the production of goods or services, restricts the technical or scientific development of goods or services, or denies market access
 - ✓ Under Section 28, the Commission may provide for divestiture or transfer of property rights including IPRs in case of a dominant firm
 - ✓ Commission may also make a reference to patent authorities under Section 21A
 - ✓ However, CL should be resorted to in exceptional circumstances



Experience of CCI

Vertical Restraints in supply chain

- The Commission has dealt with few cases involving druggists associations and their role on vertical restraints in distribution system.
- The Commission, in these cases, held that the said practices of the associations were anticompetitive in nature and therefore, ordered the associations to cease and desist from engaging in such practices and also imposed penalty/fines in some of these cases.



Vertical Restraints in supply chain (Contd..)

- The main issues/allegations involved in these cases mostly related to:-
 - Requirement of a No Objection Certificate (NOC) from the association for appointment of stockist or wholesaler. These NOCs pertained to the following:
 - ✓ Associations formulated guidelines for its members to obtain permission/NOC before which they could become a stockist of a particular company;
 - ✓ Associations forced the stockists not to sell the products of a pharmaceutical company unless NOC was obtained by them from the existing stockists of that pharmaceutical company operating in that area.

Vertical Restraints in supply chain (Contd..)



➤ The main issues/allegations involved in these cases mostly related to:-

- Associations fixed trade margins below which the stockists were not allowed to sell;
- The distributors/retailers were not allowed to give discounts to customers;
- Compulsory approval from association for introduction of drugs in the market
- Requirement for routing bids for supply of drugs to the government and the hospitals through authorized stockist only.

Unethical Practices



Doctors and Pharmaceutical Companies

- Pharmaceutical companies offering incentives to doctors
- Conference funding including foreign conferences
- Doctors even boycott drug companies not complying with their demands
- Capturing the market through inappropriate practices like collusion with doctors and their associations
- **Need for regulatory oversight**

Effects of Unethical Practices



- Unethical drug marketing influences availability, pricing and quality of drugs for the consumer
- Information asymmetry distorts competition
- Results in elimination of players who are not into such practices
- Prescribing useless medicines resulting in creation of artificial demand
- Increases cost to the patients
- Reduces the choices available to patients/doctors



Pharma. Mergers-Experience of CCI

- The Commission has dealt with more than 10 **notifications in the pharmaceutical sector.**
- Most important being the proposed merger between Sun Pharmaceutical Industries Limited and Ranbaxy Laboratories Limited (First phase II case)
 - Relevant Market – Formulations based on same API constitute a relevant markets on the basis of substitutability.
 - Investigation focussed on forty nine relevant markets along with two pipeline products and market for APIs.
 - On the basis of its assessment, the Commission approved the proposed merger between Sun Pharma and Ranbaxy, subject to divestiture of seven products.



Case Study



Case No C-2014/05/170 –

- Merger of Ranbaxy Laboratories with Sun Pharmaceuticals
- 2nd and 5th largest pharmaceutical companies in India
- Transaction will create
 - 5th largest global generic pharma company
 - Largest pharma company in India

Assessment

- Formulations based on 49 molecules were shortlisted primarily on the basis of HHI.
- These were further studied on the following parameters to assess any AAEC:
 1. Combined market share;
 2. Incremental market share;
 3. Pre & Post merger value of HHI and change therein i.e. level of concentration in the market and changes therein;
 4. Market share of next competitor;
 5. Number of other competitors who have a market share of more than 5% in the market;
 6. Whether one of the parties is already the market leader
 7. Likely imminent & sufficient entry

Assessment

Import Substitution

- Imports of formulations are primarily for R&D purposes and not for retail sales.
- Imports substitution is not possible.

Entry Barriers

- Regulatory barriers are relatively insignificant in India.
- As per parties submissions, in certain cases manufacturing process is complex and difficult to replicate resulting in technical barriers to entry.
- Markets for many of the molecules are highly concentrated, indicating that effective entry is not easy.
- Unethical marketing practices make it difficult for competitors to enter/ sustain in the market.

Degree of countervailing power

- Patients do not have a choice in deciding which products to buy
- Large number of prescribing doctor and the patient resulting in scattered countervailing power.

Decision of the Commission

- On the basis of its assessment, the Commission concluded that the proposed combination is likely to cause AAEC in 7 molecules.
- Accordingly, the Commission resorted structural remedies and asked the parties to divest these molecules.



Pharma. Mergers-Experience of CCI

- Three legged combination between **GlaxoSmithKline plc (GSK)** and **Novartis AG (Novartis)**
 - Acquisition of the global human vaccines business of Novartis (excluding its influenza vaccines business) by GSK;
 - Formation of a consumer healthcare joint venture (J.V.) between GSK and Novartis; and
 - Acquisition of GSK's oncology business by Novartis:
 - Parties claim - the oncology pharmaceutical products should be differentiated on the basis of the type/stage of cancer, line of treatment and mechanism of action;
 - The Commission sought expert opinion from the leading hospitals in India who opined that oncology products of the GSK and Novartis cannot be used interchangeably during the course of treatment of the patients in India and thus there is no overlap.



Pharma. Mergers-Experience of CCI

- Commission has analyzed non-compete clauses in cases and noted that :

“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”

- In these cases, the Parties reduced the *period* as well as *scope* of the non-compete obligation so that the restrictions imposed are reasonable.
- The Commission took a balanced view to protect consumer welfare as well business interests .



Way Forward

- Need for greater awareness among the market participants in the pharmaceutical sector about the importance of competition in the market and the requirement of the Competition Act
- Architecture of the Act also allows the Commission to take up the matter *suo-moto* as and when any possible violation of the provisions of the Act
- Strengthening oversight of healthcare sector through regulation to curb malpractices



THANK YOU



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