



Competition Law & Pharmaceutical Industry

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About CENTAD

- Undertakes policy research and advocacy on issues related to trade and development, with a primary focus on South Asia.
- Centad's work on access to medicines currently focuses on issues pertaining to access in India and aims to
 - Secure a legal and policy environment to ensure access to medicines.
 - Ensure transparency and accountability in public spending on drugs.
 - Examine the impact of industry practices on access. 2



Focus of the Presentation

- Bring to light anti-competitive practices prevalent in the pharmaceutical industry and healthcare sector.
- Indicate the approach proposed to be taken for executing the study and analyzing the data collected in pursuance thereof.



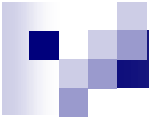
Broad Scheme of Presentation

- Indian Pharmaceutical Industry a Snapshot
- Access to Medicines Situation in India
- Objectives of the Study
- Anti-competitive Practices Competition Act 2002
 1. Regulation of Combinations
 2. Anti-competitive Agreements
 3. Abuse of Dominance
- Proposed Chapterisation
- Proposed Methodology



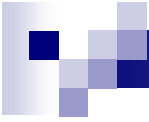
Indian Pharmaceutical Industry a Snapshot

- Net Worth 8 Billion Dollars
- Growth Rate of 8-9% PA.
- 4th in the World in terms of Volume of Drug Output
- Exports to nearly 212 countries @ USD 4795.33 million (2005-06)
- Has an important role to play in promoting public health and Right to Health.
- Highly technology and knowledge intensive.



Indian Pharmaceutical Industry a Snapshot

- Industry growth highly dependent on the regulatory environment .
- Owes its current growth and success to the Patents Act of 1970 which abolished product patents in the pharmaceutical sector. The same helped
 1. Reduce the manufacturing costs in terms of license fee
 2. Reduce the costs involved in R&D
 3. Diffusion of technology and knowledge through reverse engineering



Indian Pharmaceutical Industry a Snapshot

- There is no single market .
- The market is divided into therapeutic segments. i.e. vitamins, respiratory disorders, cardio ailments, anti fungal , antibiotics etc...
- No consumer choice. The consumer is dependent on the information provided by the pharmacist and the doctor.



Access to Medicines Situation in India

- Country with largest number of people (649 million) without having access to essential medicines.

*(World Medicine Report (2004) of World Health Organization)


- Private expenditure (out of pocket) of the total expenditure on health is one of the highest in the world – 84%.
- 50% of health care costs pertain to expenditure in buying medicines.
- 28% of rural population (up from 24% in 1995-96) did not take any treatment due to financial problems.

*(The NSS morbidity survey of 2004 (Report no 507))

- Out-of-pocket medical costs alone may push 2.2% of the population below the poverty line in one year.

*(India - Raising the Sights: Better Health Systems for India's Poor, World Bank, May, 2001)

- Affordability an important issue as far India is concerned.



Objectives of the Study

- Identify anti-competitive activities prevalent in the pharmaceutical market.
- Identify areas and practices which fall within the Commission's regulatory ambit.
- Explore ways and means to use Competition law and policy to enhance consumer access to medicines and secure a competitive environment in the industry.



Approach to the Study

- A statutory analysis of the market practices and industry behavior in the pharmaceutical industry and healthcare sector. (Competition Act – 2002)



Anticompetitive Practices & Competition Act 2002

- Regulation of Combinations
- Anti-competitive Agreements
- Abuse of Dominance



Regulation of Combinations

- Regulation of Combinations – Statutory Provisions
- Mergers - Competition Tribunal of the Republic of South Africa
- Pharmaceutical Mergers and Acquisitions – India
- Combinations & Implications for Innovation Markets
- Relevance of Competition Law



Regulation of Combinations – Statutory Provisions

- The Act prohibits any person or enterprise from entering into a combination which could cause or is likely to cause an appreciable adverse effect on competition in India. *(Sec.6 (1) of the Competition Act, 2002)
- The Commission is empowered to declare such combinations as void.
- The commission can look into the merger or amalgamation upon receiving a notice from the parties or a statutory authority.



Regulation of Combinations – **Statutory Provisions**

Parameters for the Commission to Investigate Combinations

- Barriers to entry into the market. *(Section 20.4.b. of the Competition Act, 2002)
- Extent to which substitutes are available or are likely to be available in the market. *(Section 20.4.g of the Competition Act, 2002)
- Likelihood that the combination would result in the removal of a vigorous and effective competition or competitors in the market.
*(Section 20.4.i. of the Competition Act, 2002)
- Implications for the nature and extent of innovation.
*(Section 20.4.l. of the Competition Act, 2002)
- The commission can either approve the said combination or reject the same.
- In the alternative the Commission can also propose modifications to the terms of the combination.

Mergers - Competition Tribunal of the Republic of South Africa

Merger between Glaxo Wellcome plc and Smithkline Beecham plc

	ANTIVIRALS (EXCLUDING HIV) (J5B)	TOPICAL ANTIBIOTICS (D6A)	ANTI-EMETICS (A4A)
SMITHKLINE BEECHAM'S SHARE	Famciclovir 17,5%	Bactroban 55%	Granisteron ("Kytril") 5,2%
GLAXO WELLCOME'S SHARE	Zelitrex 40,2% Zovirax 27,8%	Polysporin 5% Cicatrín 4,3% Neosporin 0,5%	Zofran 22,4% Valoid 10,6%
POST-MERGER MARKET SHARE	85.6%	65.3%	38.2%

- The merging parties have agreed to out license products in each category to address the competition concerns.



Pharmaceutical Mergers and Acquisitions – India

- Right now the market is highly fragmented
- Mergers and acquisitions could lead to consolidation of market shares
- April - Acquisition of US – Based Draxis Health Inc by Jubilant Organosys – (\$ 255 million)
- May – Buyout of Dabur Pharma by Fresenius Kabi (German Company for \$218 million)



Pharmaceutical Mergers and Acquisitions –India

June – Acquisition of 51% stake in Ranbaxy by Daiichi Sankyo Company Ltd , Japan

- Deal valued at Rs.19,780 crores.
- Ranbaxy valued at 8.5 Billion Dollars
- Ranbaxy to become an independent generic arm of the company
- Daiichi primarily looked at Ranbaxy's marketing network in 60 countries as opposed to its (21 countries)
- Ranbaxy to benefit from Daiichi's research strengths.



Relevance of Competition Law

- Acquisition of the only generic companies with the wherewithal to manufacture variants could have adverse implications for availability of off patent drugs.
- May Have Adverse Implications for Specific Therapeutic Areas.
- Drugs worth more than \$ 90 billion are going off patent in the near future.
- Could lead to perpetual extension of the term of the patent because of absence of competitors.



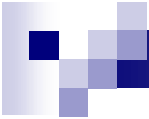
Combinations & Implications for Innovation Markets

- Combinations (mergers & amalgamations) have grave implications for ‘innovation markets’
- ‘An innovation market consists of the research and development directed to particular new or improved goods or processes, and the close substitutes for that research and development’
- They may pose a threat for subsequent entry of products by stifling competition at the R&D and product development stage.



Anti-competitive Agreements

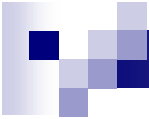
- Anti-competitive Agreements – Statutory Provisions
- Anticompetitive Agreements - Collusive Activities
- Drug Prices & Collusive Activities
- Anti Competitive Agreements – Cartels
- Anti Competitive Agreements - Patent Settlements - Abbott/Geneva
- *Anti Competitive Agreements - Tie Up Agreements for Supply of Active Ingredients - FTC v. Mylan Laboratories Inc*



Anti-competitive Agreements – Statutory Provisions

- “ No enterprise or association of enterprises or person or association of persons shall enter into any agreement in respect of production, supply, distribution, storage, acquisition or control of goods or provision of services, which causes or is likely to cause an appreciable direct effect on competition within India”.

*(Section 3(1) of the Competition Act, 2002)



Anti-competitive Agreements – **Statutory Provisions**

- The Competition Act (Section 19(3) of the Competition Act, 2002) requires the Commission to take due consideration of the following parameters before declaring certain agreements as anti competitive, namely
 - a. Creation of barriers to new entrants in the market
 - b. Driving existing competitors out of market
 - c. Foreclosure of competition by hindering entry into the market
 - d. Accrual of benefits to consumers
 - e. Improvement of production or distribution of goods or provision of services
 - f. Promotion of technical, scientific and economic development by means of production or distribution of goods or provision of services



Anticompetitive Agreements – Collusive Activities

- Collusive Activities (Manufacturer and Health Service Providers)
- **Manufacturer – Doctor** - (Incentives for Prescribing Irrational Combinations, Prescribing Expensive Brands)
- **Manufacturer – Pharmacist** – (Colluding to clear a particular drug despite availability of cheaper variants)
- **Tied Selling Practices** - Manufacturer – Doctor – Pharmacist
- Manufacturers and Hospitals



Drug Prices & Collusive Activities

- The DPCO 1995 allows 16% margin to retailers and 8% margin to whole sellers for the scheduled formulations.
- No such limit has been fixed in respect of non-scheduled formulations.
- The percentage of drugs under the DPCO's ambit coming down.
- Companies shifting production away from price controlled categories

Drug Prices & Collusive Activities

DPCO Year	No. of Drugs under Price Control	Percent of Market Covered in Price Controlled Category (approx.)	Mark-up (profitability) allowed
1979	347	80-90%	40%, 50% and 100% in three categories termed "life saving", "essential" and "non essential"
1987	142	60-70%	75% and 100% in two categories, subsequently one category with 100% mark up
1995	74	25-30%	100%
2002	20-25	10-20%	100% or more

*Source: Centad Study on Pricing. Successive DPCOs and 2002 Policy Document.
 Calculation of market share is approximate and based on ORG data
 for relevant period.



Drug Prices & Collusive Activities

- Drug industry characterized by exorbitant trade margins
- Top Selling Brands are not the least expensive ones.
- These Brands are Pushed through Collusive Activities Between the Manufacturer, Doctor and Retailer.
- Not that affordable medicines are not produced – They are not stocked owing to collusive agreements.
- Reining in such activities will go a long way in preventing supernormal profits and allowing consumer access to affordable medications

Comparative Chart – LOCOST & Other Brands

Medicines in the market often do not reflect the real input costs

Note: Prices for 2006. December

Drug	Dose	Price in Rs. by LOCOST (per tablet)	Price of top-selling Retail Brand	Price Controlled
Amlodipine	5 mg	0.25	1.51	N
Ciprofloxacin	500 mg	1.63	8.96	Y
Enalapril Maleate	5 mg	0.30	2.60	N
Glibenclamide	5 mg	0.15	0.79	N
Fluconazole	150 mg	3.50	32.00	N
Metformin	500 mg	0.30	0.99	N
Aspirin	75 mg	0.13	0.28	Y



Anti Competitive Agreements - Cartels

- Boycott manufacturer's products till a favorable margin is arrived at.
- Enhanced margins imply higher prices for the consumers.
- Hence directly or indirectly determine purchase or sale prices.



Anti Competitive Agreements - **Patent Settlements**

Abbott/Geneva - Agreements between Branded and Generic Companies

- Abbott had a patent on Hytrin (Used to treat hypertension)
- In 1998, Abbott's sales of Hytrin amounted to \$542 million (over 8 million prescriptions) in the United States.
- Abbott's patent on Hytrin was nearing its expiry.
- Abbott projected that Geneva's entry with a generic version of Hytrin would eliminate over \$185 million in Hytrin sales in just six months.



Anti Competitive Agreements - Patent Settlements

Abbott/Geneva - Agreements between Branded and Generic Companies cont...

- Abbott paid Geneva approximately \$4.5 million per month to keep Geneva's generic version of Abbott's proprietary drug (Hytrin) off the U.S. market, potentially costing consumers hundreds of millions of dollars a year.
- Geneva also agreed not to launch the generic version till another competitor in the market undertook to do so.
- Such an agreement held anti competitive as the same prevents the entry of competitors.



Anti Competitive Agreements

Tie Up Agreements for Supply of Active Ingredients

FTC v. Mylan Laboratories, Inc

- **Complaint charged Mylan and other companies with monopolization, attempted monopolization, and conspiracy in connection with agreements to eliminate much of Mylan's competition.**
- **The alleged agreements were in the nature of tying up supplies of the key active ingredients for two widely-prescribed drugs - Lorazepam and Clorazepate**
- **Used by millions of patients to treat anxiety**



Anti Competitive Agreements

Tie Up Agreements for Supply of Active Ingredients

FTC v. Mylan Laboratories, Inc contd...

- The FTC's complaint charged that Mylan's agreements allowed it to impose enormous price increases - over 25 -30 times the initial price level for the drugs.
- For example, in 1998, Mylan raised the wholesale price of
 - Clorazepate from \$11.36 to \$377.00 (per bottle of 500 tablets)
 - Lorazepam from \$7.30 to \$190.00(per bottle of 500 tablets)
- The price increases resulting from Mylan's agreements allegedly cost American consumers more than \$120 million in excess charges.
- Mylan agreed to pay \$100 million for disbursement to qualified purchasers of Lorazepam and Clorazepate.



Abuse of Dominance

- Abuse of Dominance – Statutory Provisions
- Patents and Abuse of Dominance



Abuse of Dominance – Statutory Provisions

- No enterprise shall abuse its dominant position.

*(Sec 4.1 of the Competition Act, 2002)

- Dominant Position - a position of strength, enjoyed by an enterprise, which enables it to operate independently of the competitive forces and affect the competitors and consumers in the relevant market to its advantage.

*(Section 4.2.a. i & ii (Explanation) of the Competition Act, 2002)

- Not just dominance but an ‘abuse’ of dominant position.



Abuse of Dominance – **Statutory Provisions**

Situations Warranting an Investigation for Abuse of Dominance

- When an enterprise directly or indirectly, imposes unfair or discriminatory conditions or discriminatory prices for the purchase or sale of good or services.

* (Section 4.2.a.i & ii of the Competition Act, 2002)

- Any limitation or restriction on the production of goods or provision of services or technical and scientific development, which could prejudice the consumer interest. *(Section 4.2.b.i&ii of the Competition Act, 2002)

- Practices resulting in denial of market access are also deemed to constitute an abuse of dominant position.

* (Sec .4.2.c of the Competition Act, 2002)



Patents and Abuse of Dominance

- Dominance by virtue of operation of statute .

*(Sec 19.4.g of the Competition Act, 2002)

- The Patents Act bestows exclusive rights and could result in an enterprise enjoying a dominant position.



Patents and Abuse of Dominance

- 2005 – Product patent regime (Product patents across sectors – 20 years)
- Free hand in price fixing
- Extended patent term & delayed entry of cheaper generics
- Broad patent claims exclude competition by blocking diffusion of technology
- Threat of infringement proceedings as a tactic to keep generics out of market
- Lack of access to technology in the absence of local working requirements



Proposed Chapterisation

1. Relevance of the Study
2. Literature Review
3. Industry Profile – An Analysis of the Pharmaceutical Industry and the Market for Pharmaceutical Products
4. Role of Competition Act 2002 in Curbing the Anticompetitive Activities Affecting the Pharmaceutical Industry
5. The Interaction between Competition Law and Public Health Concerns
6. Implications of the Study for Competition Policy and Law
7. Probable Issues for Advocacy for the Competition Commission of India



Proposed Chapterisation

1. Relevance of the Study

- Relevance of the pharmaceutical industry to the healthcare sector & economy.
- Draw linkages between the pharmaceutical industry and actors involved in health care services (doctors, chemists, medical representatives, hospitals etc...) and consumer access.
- Flag the dynamics between the aforementioned players and its implications for the public health at large.
- Contextualize the role of competition law in ensuring affordable consumer access to the products of the industry and its implications for the economy and public health.



Proposed Chapterisation

2. Literature Review

- Highlight available literature on the regulatory practices in jurisdictions with established competition regimes and the way they have regulated their pharmaceutical industry.



Proposed Chapterisation

3. Industry Profile

- The background and history of the Indian pharmaceutical industry
- Give a snapshot of the current state of the Indian pharmaceutical industry
- (size of the industry, production capabilities, product profile, number of units, R&D profile, etc...)
- Analyze the pharmaceutical products from the perspective of target consumers, market information, product substitutability, market concentration etc....
- Examine the concept of 'relevant market' for pharmaceutical products.



Proposed Chapterisation

4. Role of Competition Act 2002 in Curbing the Anticompetitive Activities Affecting the Pharmaceutical Industry

- This section will examine the dynamics of the Indian pharmaceutical industry and relationship between the industry and health care providers and identify the anticompetitive behavior therein.
- Examine the anticompetitive activities identified from the perspective of the provisions of the Competition Act, 2002, and proposes suggestions by which such provisions may be utilised to curb anticompetitive activities within the pharmaceutical industry.



Proposed Chapterisation

5. The Interaction between Competition Law and Public Health Concerns

- This section examines that aspect of the pharmaceutical industry that involves its interaction with the public health and access to essential medicines.
- It also highlights the interaction between competition law and public health concerns, with a focus on issues such as government procurement, public distribution systems and price control.



Proposed Chapterisation

6. Implications of the Study for Competition Policy and Law

- Interface Competition Law with Public Health Concerns. The same shall primarily involve focusing on the interplay between the Health Policy, Pharmaceutical Policy and the Competition Law.
- Discuss the essential linkages between the current patenting regime and its implications for competition , from a transfer of technology and abuse of statutory dominance and industrial capacity and development point of view.
- A component as to how the Competition Commission of India could utilize the findings in course of identifying and regulation anti-competitive practices would be included.



Proposed Chapterisation

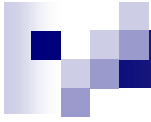
7. Probable Issues for Advocacy for the Competition Commission of India

- n This section shall highlight the plausible issues which could form part of the advocacy mandate of the Competition Commission of India.



Proposed Methodology

- Current study in pursuance of the '**structure**' mentioned in the 'Competition Assessment Framework – An Operational Guide for Identifying Barriers to Competition in Developing Countries'.
- Data on the pharmaceutical industry and market conditions will be collected using databases such as CMIE Emerging Markets, as well as industry and civil society research reports.
- Structured interviews with industry, distributors, doctors, consumer groups and other stakeholders shall be conducted as a part of the exercise.
- The comparative analysis will be carried out using online legal databases such as LexisNexis, Westlaw and HeinOnline .



THANK YOU

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