

CHAPTER III COMPETITION CONCERNS

In the last chapter, it was noted that the pharmaceutical industry and the health delivery system are afflicted by a range of market failures, the condition exacerbated by the prevalence of anti-competitive practices in the market. This particular chapter focuses on the various violations of competition norms in the pharmaceutical industry and the health delivery system.

THE PHARMACEUTICAL INDUSTRY

Intellectual Property Rights Related

The level of competition in the pharmaceuticals market is inextricably linked to a range of issues relating to intellectual property protection. The crux of the matter is that patents confer monopoly status to pharmaceutical companies as patents by their very definition grants the patent-holder exclusive rights to make, use or sell a product for a specified period. Often such monopoly rights are misused to the detriment of consumers, with companies abusing their dominant position by pricing their patented products at monopolistic profit-maximising levels, thereby severely circumscribing access to affordable medicine.

In India, with the process patent regime in place, the above-mentioned abuse of monopoly power was easily avoided. Now, however, since India has made the transition to the product patent regime from 2005, any patented products entering the market will essentially be marketed by a monopolist. This means that in the new patent regime, abuse of dominance, which was almost non-existent earlier, may become quite frequent.

The tendency of patent holding companies to abuse their dominant position in the market has particularly deleterious repercussions on developing countries. While overpricing a patented drug, companies usually do take into consideration the paying capacity of the consumer.⁵⁹ However, in developing countries, there would possibly not be substantial adherence to this policy of overweighing purchasing ability, because

to make medicines available to a large segment of the population, drug companies would have to drastically lower their prices, which they would not be willing to do.

Their unwillingness would conceivably stem from primarily two reasons. The first being that given their profit-oriented strategies, this level of reduction in prices would not be acceptable to them, and the second reason being that if they did adopt such a policy, the price differences would be so glaring that they would conspicuously reveal the extent of profits involved leading to pressure to reduce prices in developed countries as well, especially for life-saving drugs or drugs of mass consumption. Thus, it is highly likely that patented drugs in developing countries will be greatly overpriced, depriving underprivileged people in these countries from the benefits of these drugs.

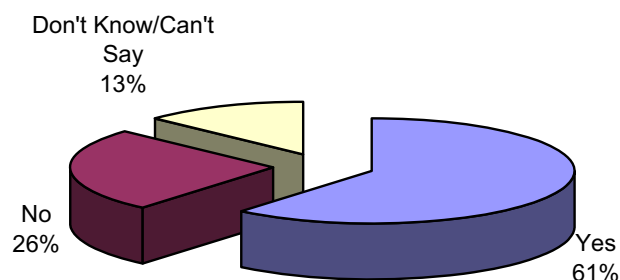
Patents and Pricing

It is difficult to predict whether or not the new patent regime will result in an increase in drug prices in India. The product patent regime having come into force only in 2005, with only one product patent having been granted till date,⁶⁰ the regime is still too new for its effect on prices to be discernible now. But consideration of certain facts, issues and situations may give us the ground to draw certain tenuous conclusions on this matter.

Firstly, let us consider the survey results. Majority of the pharmaceutical companies surveyed believe that a price rise is to be expected in the new patent regime. 40.7 percent of respondent companies predict that MNCs will price their products high in the new patent regime, with only 25.9 percent of respondents asserting that pricing policies will be based on the affordability principle. These statistics are particularly significant considering that these are impressions carried by representatives of the pharmaceutical industry itself and not consumer or NGO perceptions.

⁵⁹ See generally, Pradeep Agarwal and P. Saibaba, *TRIPS and India's Pharmaceutical Industry*, Economic and Political Weekly, September 29th, 2001

Figure: 3.1
Expected Price Rise in the New Patent Regime –
Perceptions of the Pharmaceutical Industry



In the context of patents and pricing it becomes imperative to discuss the grant of exclusive marketing rights (EMRs) in India⁶¹. Out of the seventeen applications filed for grant of EMR so far, only four have been granted in the pharmaceutical sector to Novartis's Glivec, Wockardt's tropical antibiotic Nadoxin, United Phosphorous' pesticide product Saaf and Eli Lili's Tadalafil.⁶² But the manner in which Novartis exercised these rights gives cause for concern with respect to what might be expected in the new patent regime. Novartis' Glivec is used for treatment of Chronic Myeloid Leukaemia ('CML'). There was an increase in the price of the drug from \$90 to \$2610 after the grant of EMR, which will effectively put the drug out of reach of 24,000 patients in India who suffer from CML.⁶³

This shows clear abuse of dominance through excessive pricing. It also shows the ramifications of the elimination of the process patent regime. In line with the pre-WTO practice, the Indian company NATCO Pharma Ltd. had launched in early 2003

⁶⁰ The first product patent was granted to Roche India Pvt. Ltd. - *Roche gets first product patent in India*, Financial Express, 1st March, 2006.

⁶¹ Please see p. 79 for an understanding what is meant by exclusive marketing rights.

⁶² Archa Saran, *India: A Changing Regime - India's Tryst with January 1, 2005*, 15 November 2004 at <http://194.88.95.39/article.asp?articleid=29573&searchresults=1>

⁶³ Ibid

an alternative version (named Veenat) of the aforementioned drug of Novartis. This generic version was made available to patients at one tenth the price set by the original manufacturer (estimated annual cost of treatment for Glivec at \$27000 and for Veenat at \$2700)⁶⁴.

Interestingly, Novartis now offers a programme for poor patients to whom Glivec is provided free of cost. It almost seems as if the programme is a bargaining chip to enforce their EMR,⁶⁵ so that they do not come off looking ruthlessly profit oriented. Of course, it might be that this is a truly altruistic effort and it certainly cannot be denied that the programme increases access to healthcare, but time will only tell whether the programme is philanthropic or merely a tactic designed to distract public attention away from excessively high prices.

An oft-repeated argument by pharmaceutical companies supportive of the new regime is that very few essential medicines are covered under the patent regime and, therefore, the fear that the high prices of patented drugs will block access to medicines is far greater than the situation mandates. However, essential drugs do not cover all the major prevalent diseases. For instance, the drugs used by cancer patients are not listed as essential drugs. However, a recent research publication has concluded that, out of 7.5. million new cancer cases, estimated to have occurred worldwide in 1985, the share of developing countries was 52 percent. The number of new cancers in India is estimated to be around 800,000 in 2001. The incidence among the poor also is large. In such a situation, simply because it is not treated with drugs considered as essential drugs, in no way means that there is any less need to ensure anticancer drugs at economical prices⁶⁶.

There is another case, which may be noted here. Natco Pharma is now manufacturing a generic version of AstraZeneca's Iressa, which is an anti-cancer drug. The drug priced at Rs 325 per tablet of 250 mg is at 1/10th of the cost of the international brand presently available in the market. It is conceivable that Natco could face a litigation problem as AstraZeneca is considering the drug for EMR and is in consultation with

⁶⁴ AD Damodaran, *EMR for Glivec: A TRIPS-dedicated 'Cure'?* available at <http://www.financialexpress.com>

⁶⁵ Ibid

the government agencies to do so. In all probability, the price set by Astra Zeneca will be higher than that at which Natco is currently selling the drug.⁶⁷

Box 3.1: Do Prices increase in Product Patent Regimes?

One study (1995) on Italy found that prices of new drugs increased sharply after the introduction of product patent protection in 1978. However another study (2001) arrived at the conclusion that the implementation of patent protection in South Korea, Mexico, Hungary, Taiwan and Brazil did not result in any significant rise in prices. But the latter study did not make a distinction between the new patented and the existing generic products. In fact the study did not address the vital issue, namely, were the prices of the products introduced after the product patent regime was in place higher than what they would have been in the absence of product patents.

However, the following points were raised by the chairman of the OPPI in a recent speech in contradiction to assertions that patents lead to higher drug prices.

- Patents can never be awarded retrospectively. Patents can only apply to new discoveries. Since patents of over 95 percent of the drugs available in India have expired and there are no patented drugs in the WHO List of essential Drugs, these drugs will continue to be available at current prices.
- The NPPA has power to control prices of even decontrolled drugs if found excessive

To buttress his point further, he cited studies (Study by the National Economic Research Associates-NERA, Washington-January 1998 and the Study by Dr. Heinz Redwood entitled 'New Horizons in India'-1994), which show that prices do not rise in a stricter patent regime. A study of prices in 6 therapeutic categories in 9 countries demonstrates that strengthening IPR does not have a measurable impact on real or nominal prices of existing drugs.

He also noted that at any point of time only 5-7 percent of drugs in the world market are under patent protection. The rest 93-95 percent market is of generics. For any new patented medicine, there are a minimum of 6-10 percent generic equivalents available. The price difference between the two itself acts as a control on patented drugs. Newer products, being more effective, ultimately lead to lower per day cost therapy to the patient.

In contrast to the views of the chairman of OPPI, some studies, which attempted to find out the likely effects of product patent protection on drug prices and welfare losses, came to the conclusion that the product patent regime will increase the average prices. But the extent of the price rise predicted varies a great deal. In the case of India, it varies between 12 per cent and 200 per cent.

Sources: *Sudip Chaudhuri*, The WTO and India's Pharmaceuticals Industry, *Oxford University Press*, New Delhi, 2005, p. 226; and Effect of the new patent regime on prices of medicines, speech delivered by Mr ZH Charna, Director, OPPI, India Habitat Centre, 2005

The difference in prices of generic versions of drugs and the original product is huge and this alone is indicative of increased prices in the new product patent regime. Prices of drugs may go up by 5 –10 times as is evident from the prices of drugs in India (generic versions) and the prices of drugs in other countries where product patents have been in force, such as Pakistan. To give just one example, the drug

⁶⁶ Ibid

Aciclover costs Rs. 33.75 in India while the same drug is sold in Pakistan at Rs. 363.00.⁶⁸ Therefore, that there will be a rise in prices in the wake of the new regime is, in all probability, an inevitability to be expected.

Blocking Entry of Generics

The abuse of dominance aspect of intellectual property rights in the pharmaceutical industry, which has been discussed in quite some detail above, also has certain other aspects, which include strategies adopted by companies marketing patented drugs to frustrate entry of generic rivals. Given the difficulty of ensuring access to affordable medicines, especially in developing countries, the presence of competition in the markets, particularly though generic products, is essential. Considering India's strength in the generics market, the current existence of patent holding drug manufacturers in the industry and the predicted increase in MNC patent holders in the new patent regime, the barring of generics is a definite competition concern of the present as well as the future.

Artificial barriers to block competition from generic companies would include among others the following methods aiming to lengthen market exclusivity after the expiry of a patent:

- Innovator companies having their own generics arm to stem the possible loss of business once their drugs go off patent (Pfizer's Greenstone, Novartis' Sandoz; Glaxosmithkline, Sanofi-Aventis have also developed in-house generics companies).⁶⁹ To protect their overall profits, they go to the extent of undercutting their own brands by manufacturing cheaper generic equivalents in-house or through partners.⁷⁰ While this may have predatory pricing and market pre-emption effects, often, it does facilitate access to affordable medicines.
- Injunctions to prevent legal challenges to patents, since litigation is one method used by generic producers to strip away patent rights.
- Suing (there may or may not be a legitimate cause of grievance) generic manufacturers for patent infringement so as to increase the cost of generics entering the market and discourage entry.

⁶⁷ Dr. HPS Chawla and Nalin Diwan, *The Story of EMRs-India's Response under TRIPs*, Business Briefing, Pharmatech, 2004

⁶⁸ D.P. Dubey, *Globalisation and its Impact on the Indian Pharmaceutical Industry*, available at, <http://revolutionarydemocracy.org>

⁶⁹ Bhuma Shrivastava, *US drugs going off patents in 3 years*, Business Standard, 31st August, 2005

⁷⁰ Andrew Jack, *Patently Unfair? Makers of branded drugs struggle to counter the generic onslaught*, Financial Times, November 22nd, 2005.

- Applying for excessively broad patents in order to block research carried on by competitors.⁷¹
- Launching combinations of two existing drugs as well as resorting to reformulations, modifications and new applications, gaining fresh patents in each case. The innovator companies thus keep filing for more patents of different types on their drugs to continue to enjoy exclusive rights, ‘evergreening’ in this way their existing products. The process of ‘evergreening’ of patents is accomplished by methods ranging from developing newer delivery systems and reducing side effects to shifting the drugs to over-the-counter (OTC) and identifying additional uses of the drug, not evident when the drug was first approved and priced.⁷²
- The use and aggressive marketing of brand name to increase barriers to entry for generic drug manufacturer

Box 3.2: Block or delaying generic competition –Certain Cases

Recently, the European Commission has started investigating pharmaceutical companies in Denmark, Hungary and Italy. The firms are suspected of abusing their dominant positions by engaging in collusive conduct to delay or exclude generic competition. (*Source: Dow Jones International News, AFX International Focus, 25th October, 2005*).

Aventis Pharmaceuticals Inc. is currently facing a federal lawsuit on the charge of firstly filing a patent infringement suit against Andrx, to delay their marketing of the generic version of Aventis’ popular heart drug Cardizem CD and thereafter using another delaying tactical arrangement by paying Andrx Corp., not to market their generic alternatives. This case has originated in the United States, but practices such as these may well pervade the Indian market as well, if it has not already given that companies such as Aventis have a substantial foothold in the Indian pharmaceutical market. Aventis is ranked third amongst the MNC pharmaceutical companies of India in terms of market share. (*Source: Financial Express, May 16th, 2001*)

The pharmaceutical company Schering-Plough Corp spent US\$90mn in pay offs to generic drug manufacturers as part of a scheme to avoid facing generic competition in the market, which not only distorts the competitive process but also has serious repercussions on access to affordable medicines. (*Source: Financial Express, May 16th, 2001*)

Bristol-Myers Squibb, which has very recently set up a subsidiary company in India (Bristol-Myers Squib India Pvt. Ltd), has been indicted in the United States for using tactics, which prevented patient access to lower priced generic versions of Taxol, a treatment for breast and ovarian cancer. (*Timeline of Paclitaxel Disputes, available at www.cptech.org/ip/health/taxol/taxol-timeline2001.html*)

This practice of deterring generic competition may intensify in incidence in today’s context, as blockbuster drugs going off patent in the next three years is expected to open up a \$50bn opportunity for generic companies⁷³ and companies in possession of

⁷¹ Barbara Rosenberg, *Market Concentration of the Transnational Pharmaceutical Industry and the Generic Industries in the World: Latest trends on Mergers, Acquisitions, and other Transactions*, ICTSD-UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines, Bellagio, 12-16 October, 2004, p.10.

⁷² Supra n. 70

⁷³ Ibid

these patents are gearing up to protect their terrain by engaging in a number of competitive and anti-competitive practices.

Co-Marketing and Co-Promotion Agreements

In the context of disrupting competition from generic rivals, the matter of generic market pre-emption needs to be considered. In relation to this, examining the effects of co-promotion⁷⁴ or co-marketing⁷⁵ agreements becomes pertinent.

There is an emerging trend in India to participate in co-promotion and co-marketing agreements. Certain illustrative examples would be Aventis Pasteur's co-promotion agreement with Ranbaxy for a cluster of vaccine brands,⁷⁶ Ranbaxy and Glaxo's co-marketing agreement in the Cephalexin market covering India and Nepal⁷⁷ and Wockhardt's co-marketing agreement with Bayer AG for the marketing of the anti-diabetic drug Acarbose⁷⁸. Also INFAR India Ltd, still a 51 per cent subsidiary of the Dutch company Organon Participation BV, has initiated a dialogue with other pharma companies for co-promotion and co-marketing of products⁷⁹. Many market reports have suggested entering into such agreements in the strategies they have outlined for the purpose of strengthening the industry.

The moot question here is whether co-marketing and co-promotion agreements are pro-competitive or anti-competitive, since there exists a line of thought which considers the primary *raison d'être* of such agreements to be a strategy of innovator companies to block generic competition.

⁷⁴ Co-promotion consists of sale and marketing of a defined product under a single trademark, where the parties co-operate in managing the overall process of commercialisation, from manufacture through to sale to the ultimate consumer. (See Carlo Piria, *The Position of Co-Marketing and Co-promotion between EU regulatory and Competition Rules*, Regulatory Affairs Journal, Volume 13, No. 8, p. 653,4)

⁷⁵ Co-marketing is the sale and marketing of a defined product, which is to be conducted independently and under different trademarks by each party. (See Carlo Piria, *The Position of Co-Marketing and Co-promotion between EU regulatory and Competition Rules*, Regulatory Affairs Journal, Volume 13, No. 8, p. 653,4)

⁷⁶ <http://www.contentlinks.asiancerc.com>

⁷⁷ Pharmaceutical Sector: April 2000 Review, at www.ipan.com/reviews/archives/apr2000ph.htm - 28k - Supplemental Result

⁷⁸ Pharma-Future Diagnosed, at <http://www.equitymaster.com>

⁷⁹ Infar India in talks for marketing, promo pacts at <http://www.blonnet.com>

Analysis reveals that these agreements have both pro-competitive and anti-competitive repercussions. For example, if the alliance is between a generic drug company and a branded drug company, on one hand, it allows both companies to pool together different and often complementary skills and resources in order to compete more effectively and reduces costs, but on the other hand, these kinds of alliances may discourage other generic companies from entering the market given the much higher risks and costs created by this kind of co-operation. The single most significant competition concern in this context is market pre-emption.

It is necessary to note that evidence shows that brand name companies tend to enter such agreements with generic companies when the patent protection of a well known brand name product is about to expire. In this way the former protects itself from probable losses.

Another area of concern relating to generics' market pre-emption is that as the production of generic drugs requires some level of technology, if generic companies become only distributors of brand name products, by means of co-marketing or co-production agreements, they might stop investing in research and will not be able to *produce* its own generics. This might have a negative effect in the market if a compulsory license is granted and there is no company capable of producing the drug.

Furthermore an issue to be considered is that *any* agreement among current or potential competitors – even among generic producers – may lead to higher prices or less innovation, especially when they imply a coordination of policies that include pricing.⁸⁰

GlaxoSmithKline recently entered into licensing agreements with two American generic producers - allowing them to produce “authorized generics” - right after the announcement of a poor result for the first semester of 2004, caused by generic competition that knocked US\$1.4bn off sales of its two blockbusters. Even though such deals provide the company with modest revenue, half of its losses may allegedly

⁸⁰Supra n. 71

be recovered due to them, as well as by the introduction of Glaxo's own generic, as this strategy is supposed to deter entry of other generics.⁸¹

Therefore, while co-marketing and co-promotion agreements can, on one hand, reduce barriers and accelerate generics entry in the market, on the other, they are likely to prevent long run entry as well as reduce real competition among brand names and generic firms –which may be truly costly particularly for developing countries.

The generic drug market exemplifies a competitive market (there being many players involved and a homogenous product range) and the affordability of generic products mandates that these markets be particularly sheltered from the prevalence of anti-competitive practices.

The eminent economist, Joseph E. Stiglitz has said, “Intellectual property protection strengthens dynamic efficiency and competition, but often at the expense of static efficiency and competition. If overly strong, it can actually hinder both dynamic and static efficiency and competition.”⁸² Another key statement which exemplifies the dynamics existing between patents and competition is as follows: “While patent law attempts to protect the monopoly right of excluding third parties from exploiting the patent, antitrust law attempts to prevent monopolies, encouraging competition.”⁸³ It is important to note that all this need not necessarily mean that the two fields are in conflict. IPRs promote dynamic efficiency and thereby improve welfare while fair and free competition improves overall market efficiency.

Considering that the research and development process for new drugs is costly and risky, without a minimum protection of their initial investment in creating a new molecule, there would be no incentive for drug manufacturers to engage in R&D work. All this is especially vital in the context of increasing resistance to existing drugs and new diseases being discovered. It is necessary to appreciate both the positive and negative aspects of intellectual property rights without being overwhelmed by the dimensional considerations of either. The crucial issue here is

⁸¹ Ibid

⁸² Joseph E Stiglitz, *Public Policy Towards Intellectual Property*, International Computer Law Adviser 6, June 1991, p. 6.

⁸³ Supra n. 71

how to achieve the perfect balance in interpreting and implementing IPRs and competition law so as to facilitate access to medicines and enhance both static and dynamic efficiency. This is proving a challenge to competition agencies across the world. In India, this issue remains largely unexplored. However, given the new patent regime, a close examination of all modalities involved and associated with this issue must be done soon.

Mergers & Acquisitions

As of now, the Indian pharmaceuticals industry is highly fragmented. It is expected, however, that the coming years will see intense consolidation activities. In fact, most of the top global pharmaceutical companies are consolidating their market positions, either through product rationalisation, brand acquisitions, or company acquisitions. Companies are re-evaluating their strengths and emphasising product segments that are profitable.

Whilst many domestic companies are enhancing their product portfolios by expanding therapeutic reach through product launches in new high margin segments, many others are trimming their portfolios to focus on particular therapeutic segments. Aventis, Glaxo SmithKline, Wockhardt and Ranbaxy have cut down their product portfolios in order to be more focused. Sun Pharma, Nicholas Piramal and Dr. Reddy's Labs have opted for brand/company acquisitions to increase their therapeutic reach and market penetration. Large Indian pharmaceutical companies are also expanding their reach overseas through acquisitions abroad. Examples include Ranbaxy's acquisition of RPG Aventis; and Wockhardt's acquisition of CP Pharmaceuticals.⁸⁴

Pressure to reduce drug prices has made pharmaceutical TNCs resort to mergers and alliances, in a bid to reduce R&D duplication & costs, combine product portfolios and increase reach. The total number of alliances increased from 120, in the mid-1980s, to nearly 400 in the mid-1990s. These alliances often allow pharmaceutical companies to draw upon each other's research expertise, and bring products to market more rapidly and more effectively. The mega-mergers in the global pharmaceuticals industry, in the

⁸⁴ Supra n 10 at p. 198

last few years, have been Sanofi-Aventis, Glaxo-Wellcome-SmithKline Beecham; Hoechst-Marion-Merrell Dow-Roussel; Pfizer-Warner Lambert; Ciba-Sandoz (to form Novartis); and Hoechst Marion Roussel-Rhone Poulenc (to form Aventis). The trend is expected to continue, and such mega-mergers in the global market are likely to raise competition concerns in several markets, including India.⁸⁵

Expectedly, Indian pharmaceutical industry has seen several cases of M&A over the last few years, both as a direct fall out of mergers of global players, as well as M&A of domestic players, and in some cases between global and domestic players. Several of these cases involved companies that had medicines that were used for the same therapy and hence were competing directly. The following table cites few such cases where the companies involved were a dominant or a major player before or/and after the merger. It was not possible to infer if the market power was pre-existent or achieved after the merger due to non-availability of historical data.

Table 3.1: Companies in M&A and their competing medicines

M&A & Companies	Therapeutic Category/Therapy	Company	Medicines
Nicholas Piramal (India) (NPI) Boehringer Mannheim (BM)*	Cardiovascular System: <i>1. Cardiac Disorders</i>	BM	Calaptin, Calaptin INJ
		NPI	Mono Sorbitrate 20/40
		BM	Calaptin, Calaptin INJ, ISMO-20
	<i>2. Aginal Drugs & Coronary Vasodilators</i>	NPI	Cardules, Sorbitrate
		BM	Calaptin, Calapin INJ, Calaptin-240 SR, Sembrina-250
	<i>3. Anti-hypertensive</i>	NPI	Cardules
		NPI	Aquaviron B-12, Multigesic
	Hormones: <i>Gonadal Hormones</i>	BM	Euglucon
	Nutrition: <i>Vitamins</i>	NPI	Betavite Forte
	Metabolism: <i>Poisoning & Metabolic Dysfunction</i>	BM	Mittavin
NPI		Bezalip	
Pharmacia (Boots Pure Drugs- Boots Company (India) Limited - Boots Pharmaceuticals Limited - Knoll Pharmaceuticals Limited - Abbott India Limited) Pfizer	Nutrition: <i>Vitamins</i>	Abbott	Bevidox Injection
		Boots	Betonin, Kinetone
		Pfizer	Becosules
	Musculo-Skeletal Disorders: <i>Non-steroid Anti-inflammatory Drugs</i>	Pfizer	Dolonex
		Boots	Brufen, Froben, Froben-SR
	Respiratory System: Expectorants, cough suppressants, mucolytics & decongestants	Pfizer	Corex
Boots		Protussa Plus	
Nicholas Piramal (India) (NPI)	Cardiovascular System: <i>1. Aginal Drugs & Coronary Vasodilators</i>	RP	Sectral-200
		NPI	Cardules, Sorbitrate

⁸⁵ Ibid

M&A & Companies	Therapeutic Category/Therapy	Company	Medicines
Rhône Poulenc*	2. <i>Anti-hypertensive</i>	RP	Sectral-400
		NPI	Cardules Retard
Glaxo India Burroughs Wellcome (India) Limited - BWIL	Infections & Infestations: <i>Antibiotics</i>	BWIL	Aerosporin, Cefizox
		Glaxo	Ceporan, Crystapen, Fortum, Phexin, Supacef, Supacef Captabs
	Respiratory System: 1. <i>Bronchospasm relaxants</i>	Glaxo	Salbutamol Inhaler, Ventorlin
		BWIL	Theo-PA
	2. <i>Expectorants, cough suppressants, mucolytics & decongestants</i>	Glaxo	Piriton Expectorant, Ventorlin Expectorant, Protussa Plus
		BWIL	- Actifed, Actilex
	Skin: <i>Topical Steroid Preparations</i>	Glaxo	Benovate, Benovate, Scalp Application, Benovate-C, N, Eumosome, Tenovate-M, Tenovate Skin cream
		BWIL	Neosporin Oint.
	Cardiovascular System: 1. <i>Cardiac Disorders</i>	Glaxo	Sotagard
		BWIL	Lanoxin/Digoxin
		2. <i>Aginal Drugs & Coronary Vasodilators</i>	Glaxo
BWIL			Cardilate
Hindustan CIBA Geigy Ltd. – HCGL Sandoz (India) Ltd. - CLARIANT (INDIA) LTD.*	Cardiovascular System: 1. <i>Cardiac Disorders</i> 2. <i>Aginal Drugs & Coronary Vasodilators</i>	HCGL	Lopresor Tablets, Trasicor
		Sandoz	Visken
	3. <i>Anti-hypertensive</i>	HCGL	Adelphane, Adelphane-Esidrex, Esidrex, Lopresor Tablets, Nepresol, Serpasil, Trasicor
		Sandoz	Brinaldix, Visken

* Both the companies involved were highly active in some other therapeutic categories. However, further details were not available.

Source: CIMS, Manish Agarwal, *Analyses of Mergers in India*, MPhil Dissertation, University of Delhi, 2002, Websites of the companies.

What then are the anti-competitive practices, which may be expected as a result of mergers and acquisitions? Why is it essential to examine all the modalities and possible repercussions of a desired merger before sanctioning the process? Mergers are not necessarily anti-competitive and may lead to creation of efficiencies. The trends of mergers and acquisitions in the global pharmaceutical market seem to reveal that for the pharmaceutical industry, these transactions are an appropriate way of counteracting competition and achieving more profitable returns and high market shares.⁸⁶

However, the concern is whether the mergers, the acquisitions or the joint ventures will enable parties to achieve or strengthen a dominant position in the markets in which they compete and whether there will be abuse of dominance leading to higher prices, reduced output or less innovation. To cite just one example of possible anti-

competitive ramifications: such transactions may eliminate a significant direct competitor in a relevant therapeutic category, particularly where there are few substitutes and new entry is difficult. This is often the case in many pharmaceutical markets, due to technological and regulatory impediments to entry.

As not permitting the establishment of dominant structures in the market is an effective preventive method, mergers and acquisitions should be subjected to careful scrutiny. A particular cause of anxiety is that these processes often lead to patent pooling, which gives rise to the possibility of abuse of dominance with respect to their combined intellectual property rights.

Mergers and acquisitions can raise competition concerns, whether they combine two producers of competing branded products, producers of branded and competing generic products or two products of competing generic products.

In this context, it is worth mentioning that the particularities of the pharmaceutical market require that attention is given not only to transactions involving companies competing in the same market, but also to transactions that may be inhibiting future competition, either by increasing barriers to generic entry or causing potential harm to innovation.⁸⁷

Till date there has been no outright ban on any proposed merger. In a few cases the mergers did result in the parties to the merger acquiring too much market power for some of the products involved. The parties, however, eased the concern demonstrated by the authorities by means such as offering partial divestitures, and delivering on promises to outlicense relevant products. Such accommodations were involved in the case of the merger involving Rhone Poulenc and Hoechst and also in the merger involving Glaxo Wellcome/Smithkline Beecham.⁸⁸ The latter case, of course, has many other dimensions as well and has been discussed subsequently in more detail.

⁸⁶ Supra n. 10

⁸⁷ Ibid

⁸⁸ Mario Monti, *EC antitrust Policy in the Pharmaceutical Sector*, 2001, available at europa.eu.int/comm/competition/speeches/text/sp_2001_013_en.pdf

At present, it would appear that mergers and acquisitions cannot easily lead to the creation of a dominant position as globally no one company has a market share of more than 11 percent. In fact, there is only one company, Pfizer which has a percentage share of the global market in excess of a two-digit figure⁸⁹. However, data relating to market shares at a global scale are hardly indicative of absence of concentration, since when one studies the relevant markets, i.e., therapeutic categories of medicines; there are several cases of high levels of concentration.

Significantly, the consolidation in the global generic industry following Teva's acquisition of Ivax and Sandoz's takeover of Hexal has created a huge gap between the top two generic players and the rest of the industry⁹⁰. Analysts have opined that if Ranbaxy can takeover or tie up with a large company, it could become the third-generics company in the world⁹¹. Whether the gap between these companies and the others in the generics market may in the future give rise to anti-competitive concerns remains to be seen.

In India, the new competition legislation provides for merger review beyond a threshold level. As the threshold level is reasonably high, only the big deals will come under the scrutiny of the competition authority. This does not necessarily mean that all such deals need to be blocked. The deals, however, will require complex analysis to examine the impact of the deal on different therapeutic segments. For example, Glaxo-Wellcome-SmithKline Beecham was allowed to merge by the EU, on the condition that they divested product categories where competition concerns could arise. The deal went unchallenged in most developing countries. However, South Africa, who closely cooperates with the EU, imposed similar conditions before it allowed the merger of their local subsidiaries. This shows how India can deal with merger and acquisition cases, not only of domestic companies but also of global companies, with local presence in India.⁹²

⁸⁹ Supra n. 16

⁹⁰ Javed Sayed, *Pharma cos snap up \$ 500-m buys in 18 months*, Economic Times, September 4th, 2005

⁹¹ Ibid

Box 3.3: Mega-merger – Glaxo Wellcome and SmithKline Beecham

Two large pharmaceutical giants, Glaxo Wellcome, and SmithKline & Beecham, merged to become GlaxoSmithKline (or GSK). This merger created a leading global pharmaceutical company, with sales of £18.1bn in the year 2000. Headquartered in the United Kingdom, GSK supplies products to 140 markets in the world. Obviously, the merger created competition concerns in several countries, yet it went unchallenged in most of them. India did not have a merger review provision in its extant competition law, the MRTPA, so the merger was not investigated. In Sri Lanka, the competition authority did not even take up the case of merger between Glaxo Wellcome and SmithKline Beecham, saying that that it did not have jurisdiction, even though both the companies had commercial presence in the country!

The handling of the merger case by South Africa is quite illustrative. Upon investigation and evaluation of the merger, the Competition Commission reached the conclusion that the transaction should be prohibited, on competition and public interest grounds. In particular, the Commission was concerned that the merger would result in the merging parties having high market shares in two therapeutic categories. The Commission stipulated that there would be unacceptable levels of concentration with respect to Bactroban, Zelitrex and Famir, and there were no appropriate substitutes to counter any price gouging, or ease of entry, to offset the concern.

Upon prohibition of the merger by the Commission, the merging parties volunteered to out-license some of their products identified, by the Commission, to be the cause of the competition concerns. The merging parties, and the Commission, reached an agreement and the merger was allowed, conditionally. Interestingly, the conclusion of the Commission, in making its recommendations to the Competition Tribunal, was substantially the same as the conclusions of the EC, in so far as the overlap of products was concerned. This may partly be due to the fact that the Commission sought, and received, extensive cooperation from both the US and EC. However, it may be noted that the Commission completed its investigation long before the case was decided by the EC.

Source: Nitya Nanda and Amirullah Khan, Competition Policy for the Pharmaceutical Sector in India, in “Towards a Functional Competition Policy for India”, Pradeep Mehta (ed), Academic Foundation, New Delhi, 2006.

Notwithstanding all of the above while mergers may or may not have anti-competitive effects, they are necessary for many companies to remain in the competition. Consider the key drivers of the increasing tendency to merge, rising R & D costs, decline in the number of new product launches, pressure from expiry of patents on existing products, need for improvement in sales and marketing, access to new markets, healthcare cost-containment efforts of governments affecting the pricing power of the company and the desire to achieve economies of scale.⁹³

⁹² Supra n. 10

⁹³ Amul Gogna, *It can provide companies access to new markets*, The Financial Express, June 27th, 2005.

In the new product patent regime, while the bigger Indian companies, such as Ranbaxy and Dr. Reddy's can afford to develop and market their own brand of drugs in the highly competitive regulated markets, the same is not the case with small and middle-rung companies. They do not possess the financial capacity to survive in the rapidly changing market environment and takeovers, strategic tie-up, mergers and marketing alliances allow them to survive⁹⁴. While the bigger companies undergo mergers and acquisitions for further expansion and profits, SMEs do the same to remain competitive. With almost all multinationals expected to set up their facilities in India or start marketing their patented products, it is predicted that competition will become intense⁹⁵.

Given that the bulwark of the Indian pharmaceutical sector, the process patents system, is now in the past, it is essential to develop sound survival strategies and for the Indian pharmaceutical sector, mergers and acquisitions is one route being resorted to. In fact, since January 2004, Indian pharmaceutical companies have made 18 international acquisitions with an aggregate deal value of more than \$500mn approximately. And with companies of the likes of Ranbaxy and Wockhardt predicted to seek "big-ticket" M&As, the figure is set to rise⁹⁶.

It is necessary to mention that bigger companies often seek M&As to maintain or increase their market shares, which may in the long run have possible anti-competitive effects if a dominant position is created; examples in this particular context would be Teva scouting for a big acquisition in India which will help it in regaining its top position in the global generic pharmaceutical market. Teva lost this position after Novartis bought over Hexal in a \$8.3bn deal.⁹⁷

Keeping in mind the slew of mergers happening and slated to occur, the benefits such mergers entail and the possible anti-competitive effects, competition authorities need

⁹⁴ P Vinod Kumar, *Drug companies go for second rung of foreign acquisitions*, Financial Express, 19th August, 2005.

⁹⁵ See generally, *M&As can help launch new molecules*, The Financial Express, June 27th, 2005. Also see Giteesh Chandra Prasad & Javed Sayed, *Pharma MNCs to have strategic tie-ups here soon*, Economic Times, April 7th, 2005.

⁹⁶ Supra n. 90

⁹⁷ Rajesh Unnikrishnan, *Global generic drug cos descend on India*, Financial Express, March 13th, 2005.

to carefully analyse the probable repercussions of a proposed merger before permitting or for that matter disallowing the process to go ahead.

Collusion and Other Anti-Competitive Practices

Collusion

Collusive activities can range from cartelisation to bid rigging. Collusive activities among Indian manufacturers of pharmaceuticals have not yet been discovered. However, existence of a tendency towards collusive behaviour in certain segments, where there are just a few manufacturers, cannot be ruled out, particularly when an international cartel in bulk vitamins was in existence for quite a long time. According to one estimate, this vitamins cartel cost India about US\$25mn, in the 1990s, due to overcharging.⁹⁸ There may have been the incidence of other cartels as well affecting the pharmaceutical industry which have remained undiscovered till date. Further pernicious effects of cartels, international or domestic, may be felt in the future.

Box 3.4: Collusive Practices – A Brazilian Case Study

The following case study illustrates collusive conduct in the pharmaceutical industry and is significant, because most of the companies involved in this case have a foothold in the Indian industry as well. Twenty pharmaceutical laboratories were recently fined by competition authorities in Brazil, for participating in a cartel, which allegedly attempted to boycott the entry of new generic medicines. The laboratories involved include large multinational groups such as Roche, Aventis, Bayer, GlaxoWellcome and AstraZeneca. The intention of the cartel was to establish a joint action- involving general practitioners-to develop an information campaign against generics, thereby spreading what was regarded as, “distorted information”. This case reveals collusion between pharmaceutical companies and doctors on the matter of barring generics, an issue of grave concern since patients usually implicitly rely on the advice meted out by their physicians and in such a case may be deprived of quality products at less expensive prices.

Source: 20 Pharma Laboratories Fined for Cartelisation, Folha News, 13th October 2005.

One case illustrates the kind of price fixing practice companies engage in. In the United States, Mylan, a maker of generic drugs was accused of price fixing with its suppliers pushing up the cost of medicines 3000 percent.⁹⁹ This might be a problem in India as well, with companies making their stance against the fixing of trade margins for generic drugs apparent. In another case the US State of Pennsylvania sued a slew of pharmaceutical companies for artificially inflating prices and the use of deceptive

⁹⁸ Supra n 10

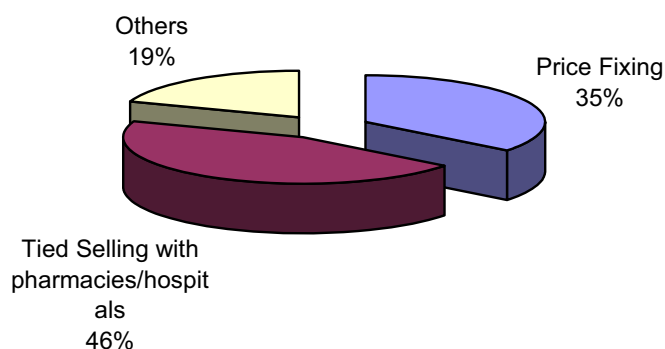
⁹⁹ Mylan and others-Another Drug Cartel, available at Antitrust Regulators Crack Down on Health Industry, Los Angeles Times, December 22nd, 1998

sales practices.¹⁰⁰ These companies include a number of MNCs, which have a significant presence in Indian markets, such as AstraZeneca, Bayer, GlaxoSmithKline, Pfizer and Bristol-Myers. Cartelisation through cross licensing is another practice, which exists in the industry and affects fair and free competition.

Table 3. 2: What Pharmaceutical Industry Thinks

	(Percent)		
	Yes	No	Can't say/ Don't Know
Aware of collusive practices in the industry	57.4	42.6	
Liberalisation increased the threat of collusive practices of MNCs	31.5	25.9	42.6
Felt the impact of such collusive practices	24.1	75.9	

Figure 3.2: Kind of Existing Collusive Practices - Pharmaceutical Industry



In our sample of respondents, the majority of pharmaceutical companies surveyed claimed awareness with respect to the existence of collusive practices in the pharmaceutical industry and a high 32.3 percent of respondents asserted that such practices prevail in the industry to a great extent. As Figure 3.2 indicates, tied selling was ranked as the most frequently occurring anti-competitive conduct in the pharmaceutical industry. Only 24.1 percent of the respondents admitted to having directly felt the impact of collusive practices. Given the notoriety of MNCs of

¹⁰⁰ Bayer and others defraud Medicaid Drugs, available at

engaging in anti-competitive practices and that their presence in the Indian market is predicted to increase substantially in the new patent regime, there may well be an increased incidence of collusive and other anti-competitive practices. This is a matter of concern. Industry perceptions on this issue revealed that a high percentage of companies surveyed, believe that liberalisation has increased the threat of collusive practices of MNCs.

Although there has been no documented evidence of such activities in India, the results of the survey and interviews conducted indicate that collusive behaviour is quite common in pharmaceutical markets. The vital question to consider is whether or not the absence of proof of collusive conduct in our industry reflects the reality of industry functioning or simply reveals the incompetence of our investigative institutions.

Other Practices

Providing Incentives

Giving incentives to doctors and pharmacists is one practice engaged in by companies, which blatantly violates free and fair competition. This may be motivated by a desire to create a larger market share or to gain greater profits by pushing overpriced drugs and is achieved through aggressive promotional strategies aimed at doctors, and by providing lucrative margins to chemists. Incentives to pharmacists to induce them to buy large quantities of prescription drugs have become commonplace in India, where thousands of drug manufacturers compete for shelf space, and the country's half-million pharmacists wield an unusual amount of clout. Hence, often there is a huge gap between the wholesale price and the retail price. A study by the Mumbai-based market-research firm, Interlink Healthcare Consultancy, found that all but one of the top 25 drug companies, in India, offered heavy discounting deals at least once a month. A letter to pharmacists from Blue Cross Laboratories Ltd, a Mumbai company, outlined a deal that offered pharmacists up to a 103 percent profit margin on a variety of prescription drugs.¹⁰¹

<http://www.uow.edu.au/arts/sts/bmartin/dissent/documents/health/pharmfraud.html>

¹⁰¹ See generally, Daniel Pearl and Steve Stecklow, *Drug Firms' Incentives Fuel Abuse by Pharmacists in India*, Wall Street Journal, 2001.

Box 3.5: Discounts to Pharmacists Anti-competitive?

Discounts admittedly allowed by Synbiotics Ltd., a pharmaceutical company, to its pharmacists, was held by the competition authorities in India, to be according to the mercantile practice prevailing and permissible under the law for promoting the sale of their pharmaceutical products. [2001 CTJ 45 (MRTP)] Whether discounts and rebates of this kind have an adverse effect on competition in the pharmaceutical sector is a matter of debate.

The Finnish Competition Authority has held that rebates commonly granted by pharmaceutical companies to pharmacies violate the Finnish Act on Competition Restrictions and EU competition rules. Accordingly, the FCA requested that the pharmaceutical companies concerned inform it by December 22, 2005, of measures to be taken in order to remove the unlawful features of the rebate agreements. According to the FCA's investigation, the rebates granted on the wholesale prices of pharmaceutical products restrict competition between pharmaceutical companies and curtail the choice available to pharmacy customers, particularly in respect of prescription drugs. As regards prescription drugs, the rebates relate primarily to pharmaceutical products that are substitutable with generics. According to the FCA, there are rebates in practice, which have a tying effect and limit the opportunity for competing pharmaceutical companies to obtain shelf space for their products. As of February 1, 2006, the Finnish Act on Medicines has been amended to provide that any medicinal product sold exclusively in pharmacies shall be sold at the same wholesale price to pharmacies. This means that rebates and other benefits will no longer benefit individual pharmacies, but shall be applied in respect of all pharmacies. (*Rebates by Pharmaceutical Companies Found Unlawful*, International Law Office, 2006)

Pharmacists in developed countries have little influence over the volume of prescription-drug sales¹⁰². There, the marketing push usually targets doctors, the main legal conduit for prescription drugs and give kickbacks, which can range from free airline tickets to cars.

Misdiagnosis

There are companies, which use anti-competitive methods to create a market for their product. Novartis, a company that has a large market share in India has been recently accused of fuelling the misdiagnosis of Attention Deficit Disorder (ADD) through its close association with psychiatric associations and its presentations at their meetings, and conspiring thereby to carve a niche in the market for Ritalin, their drug for ADD through expanding the use of the drug by being responsible for millions of children being misdiagnosed with ADD.¹⁰³

¹⁰² Supra n 10

¹⁰³ Novartis-Diagnosing for Profit, Writing May Be on Wall for Ritalin, InsightMag.com October 16, 2000

The major anti-competitive practices prevailing in the pharmaceutical industry having been delineated, it is necessary now to briefly overview the violations of competition principles occurring in the health delivery system.

ANTI-COMPETITIVE PRACTICE IN THE HEALTH DELIVERY SYSTEM:

The three components of the health delivery system, which has been prioritised for the purpose of this report, are doctors, pharmacists and hospitals. Diagnostic laboratories are also brought into the picture as they are very often collusively linked with other components of the health delivery system. This section shall examine the anti-competitive practices widespread in their domains.

Doctors

The most significant unethical practice engaged in by doctors is irrational drug prescription. Ideally the cheapest, most readily available drugs should be prescribed. But usually the more expensive drugs are prescribed. The doctors are motivated by the kickbacks received from the pharmaceutical companies. Even if not influenced by incentives, doctors may continue prescribing a particular drug found to be effective and simply not bother to find out if there are any less expensive alternatives with the same effects. A rough estimate of irrational drug use would be 50-60 percent.¹⁰⁴ The reason why this practice is considered anti-competitive is because it impinges upon one of the basic tenets of competition policy, which is to avail of the best possible services at the lowest prices feasible.

Another practice, which is rather prevalent among doctors, is accepting commission for referrals. This may be interpreted to be anti-competitive in effect. Rational decision-making is an important principle of competition. Here the doctor is making the decision on behalf of the patient as to where best to send the patient for further treatment. Profit considerations would obviously vitiate such decision-making and herein lies the impingement on free and fair competition. However, although such practices are generally known to prevail, 76.7 percent of doctors surveyed denied being offered commission upon referral. A high percentage of 59.5 percent of doctors mentioned that other doctors take commission for referrals and 48.9 percent of these respondents felt that this practice adversely affected healthcare.

The aggressive strategies followed by the big multinational companies producing branded formulations leads to the entire branded versus generics debate in context of prescription drugs. Ensuring generic prescriptions may resolve to a great extent this practice of pharmaceutical companies influencing doctors.

Doctors as substitute consumers are certainly in a position to abuse the implicit faith many patients vest in them. Many sources confirm that this often does happen. But it must also be recognised that the choices many doctors make on behalf of their patients are motivated by welfare considerations rather than on the basis of kickbacks. Profit need not be the driving factor behind doctors not prescribing the least expensive medicine on the market or the reason for referring their patients to particular diagnostic centres, pharmacies or to other doctors. It might also be because of their awareness of greater effectiveness of a particular drug, because even if two drugs are same, their might be significant differences, for instance in their bioavailability¹⁰⁵. Certain diagnostic centres may be preferred not because of any commission consideration, but because the doctor has knowledge of comparatively superior quality services offered.

Whatever be the motivation, the vital question here is do these choices of the physician provide patients with the choice of quality goods and services at the best prices? If not, then such choices of the physician may be termed as anti-competitive.

Pharmacists

The anti-competitive practices most prominently engaged in by pharmacists are reflective of collusive behaviour. Pharmacy-owners may be considered to have banded together to form a huge cartel in the guise of a trade association, All India Organisation of Chemists and Druggists (AIOCD).¹⁰⁶ A high percentage of 64.25 percent of all pharmacists surveyed are members of the AIOCD The AIOCD is known to launch boycotts against drug companies to grab higher profit margins.

¹⁰⁴ Interview with Mr. Barun Kanjilal

¹⁰⁵ Bioavailability is a measurement of the rate and extent of a therapeutically active drug that reaches the systemic circulation and is available at the site of action.-See L Shargel, L. & A.B. Yu, *Applied biopharmaceutics & pharmacokinetics*, McGraw-Hill, New York, 1999.

¹⁰⁶ Supra n 10

As indicated by Figure 3.3, in our sample of respondents from the pharmaceutical industry, more than half of the companies admitted to facing demands from pharmacies for greater margins. Figure 3.4 shows that a high percentage of these respondents believed that these demands were on the higher side.

Figure 3.3: Companies facing demands from pharmacists for greater margins

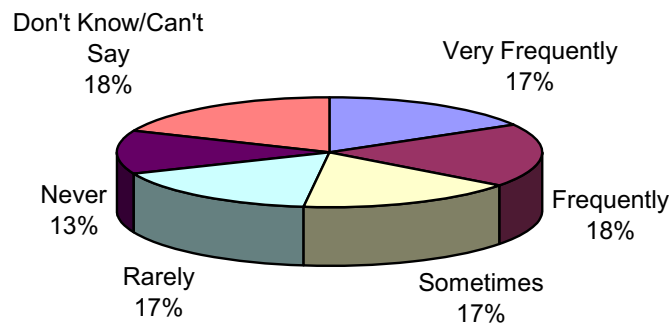
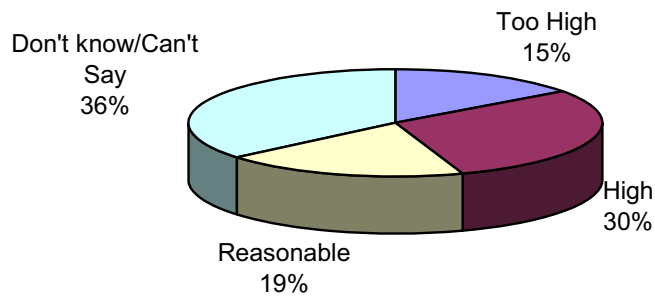


Figure 3.4: Are the demands for greater trade margins from pharmacists too high?



On the other hand, in our survey of pharmacists, not surprisingly, 79.7 percent of the respondents thought that the level of profits sought from companies was reasonable. A mere 10.5 percent of the pharmacists surveyed admitted that the profit margins sought from companies were on the higher side.

Pharmacist associations have been known to demand that drug companies obtain a "no-objection letter" from each state trade association, before a new drug could be sold there. Otherwise it would be excluded from the pharmacists' stock lists. For each new drug, the trade groups usually solicit a cash donation. AIOCD has also forced some drug companies to sign "memorandums of understanding" in which they agree to increase profit margins of pharmacies¹⁰⁷.

Box 3.6: Rent-seeking by Pharmacists: A Few Cases

Strong-arm tactics of the pharmacists' associations (at state level as well as national level) are nothing new. In 1984, a case came before the MRTP Commission as the Retail and Dispensing Chemists Association, Bombay, directed all the wholesalers and retailers to boycott a Nestle product, till the company met its demands.

The Commission observed that the impact of the chemists' boycott could, by no stretch of the imagination, be considered negligible. The boycott represents an attempt to deny the consumers certain products, which they are used to and, therefore, the hardship to such consumers is indisputable. The Commission accordingly passed a 'cease and desist' order (RTP Enquiry No. 10/1984).

Even before that, in 1982, the All India Organisation of Chemists & Druggists, had to face a similar stricture in a similar case (RTP Enquiry No. 14/1982, order dated 25-9-1984).

AIOCD was brought before the Commission once again, in 1983. It issued a circular to various pharmaceutical companies, threatening that if they dealt with the State cooperative organisations and appointed them as Stockists, granting them sale rights, it would expose the companies to a boycott by its members. The case was decided in 1993, and the Commission observed this to be the restrictive trade practice of refusal to deal (RTP Enquiry No. 37/1983, decided on 25-6-1993).

Nevertheless, undeterred, AIOCD decided to boycott the "Septran" range of products, manufactured by Burroughs Wellcome (India) Ltd. When the case came up before the Commission, AIOCD pleaded that it did not issue any such circular to the dealers, threatening to boycott the products. However, the Commission observed that a boycott could be conducted by way of an understanding among those perpetrating it, or by word of mouth among them. Merely because of the absence of a circular, calling upon the sellers to boycott, it could not be said that there was no boycott (1996, 21 CLA 322).

Recently, the MRTP commission again issued a cease and desist order against a boycott. In this case the material published in the bulletin of Retail and Dispensing Chemists Association read in one part as 'it is necessary that all retailers suspend dealing in Wander (pharmaceutical company) and ensure no retailer sells even the other products of Wander Ltd...'. The Commission held that a boycott of such nature might go against public interest by not making available an essential commodity. [1999 CTJ 436 (MRTP)].

¹⁰⁷ Supra n. 101

Price decontrol has led to greater trade margins for pharmacists. It just might be that the benefits of price decontrol, of several drugs, are going to the pharmacists disproportionately, more than the manufacturers. This defeats the very purpose of the deregulation that is meant to provide the manufacturers with the ability to spend more on R&D. By giving extra profits to the pharmacist, instead of reducing the retail price, manufacturers are keeping medicine prices higher than necessary for Indian patients.

Box 3.7: Trade Margins to Pharmacists

Statistics reveal the high level of trade margins, which pharmaceutical companies give to pharmacists. Cipla reportedly sells a strip of 10 pills of its painkiller Nicip to the retail dealer at Rs. 2 a strip. The retailer then sells it to the customer at Rs. 25 at a profit of 1,150 percent. According to information provided by Business World, Ranbaxy's anti-allergic Stanhist costs retailers Rs. 1.80 a strip. This is sold to the customer at Rs. 26. Web information provides further accounts of huge trade margins. A few instances would be as follows: 10-tablet strip of Methygin costing Rs. 5.75 sells at Rs. 54, Nimesulide in a 10-tablet strip costing Rs. 1.85 sells at Rs. 10. The following chart by NPPA gives further conclusive data in the matter of massive trade margins to pharmacists.

Company	Brand	Price printed on the strip	Purchase price of retailers
Ranbaxy	Stannist	26	1.80
Cadila Healthcare	Ceticad	26	1.60
Lyka Labs	Lycet	25	1.44
Wockhardt	Setride	25.2	1.70
Cipla	Cetcip	27.5	2.00
Ranbaxy	Pyrestat-100	25	1.50
Lupin	Lupisulide	24	1.94
Welcure Drugs	Omejel Caps	33	4.50
Wockhardt	Merizole-20	39	6.48
All figures in Rs.			

SOURCE: NPPA, as cited in FT, July 27th, 2004

It is the consumer who ultimately bears the brunt of the pharmacists receiving such high trade margins.

It is to be noted that higher trade margins are usually given in the case of generics. Drugs sold as generics maintain a large margin to compete with successful brands although they have a small market share. Typically the gap between retailer's procurement price and the retail price of drugs sold –through prescription or sales promotion through medical practitioners-vary between 5-16 per cent. But it is much higher for generic sales (direct to retailer). The cases of at least three drugs –Nimesulide (for fever and pain), Omeprazole (antacid) and Cetrizine (anti-allergic) have come to the notice of the ministry of chemicals and fertilizer. The government is now trying to rectify the situation. A meeting with NPPA was followed by a survey by the Drug Controller who discovered that the consumer was being overcharged for these three formulations

Generally see: MV Kamath: Pharmaceuticals are cheating citizens. Also see, *Govt Asks why Drug Cos are Overcharging*, Financial Times, July 27, 2004

This issue has engaged the attention of the Government. In December 2004, the Ministry of Fertilisers & Chemicals tried to bring in curbs on trade margins of pharmacists. This move was strongly resisted by AIOCD. On the contrary, they demanded for the lowering of Maximum Retail Prices, which are under the control of manufacturers. The AIOCD added that it would be impossible for them to survive on a maximum gross margin of 20 percent, excluding excise duty.¹⁰⁸ Indeed, there is some sense in the argument of the pharmacists and the manufacturers cannot avoid the responsibility, as they are the ones who control MRPs. In fact, high trade margin is not only due to bargaining power of the pharmacists but also due to manufacturers strategy to capture greater market shares through providing incentives to doctors and pharmacists.

Informal collusion by pharmacists at local level must also be considered. For example, printing of maximum retail price (MRP) is mandatory under the Standards of Weights and Measures (Packaged Commodities) Rules, 1977. MRP needs not be the actual selling price and the retailers are expected to sell at prices lower than MRP. However, in practice, the retailers do not compete and the MRP becomes the reference price for them to collude informally.¹⁰⁹

Dealing with such collusive behaviour of pharmacists will be one of the biggest challenges for the competition authority.

Hospitals

Hospitals are an important part of the health delivery system. However, not much is known about their practices, though random analysis reveals that there have been cases of agreements entered by hospitals with drug manufacturers to exploit consumers. A case that was brought in a consumer forum in Andhra Pradesh revealed that a private hospital had entered into a contract with a drug manufacturer to supply drugs to the hospital at prices, which were above the market price. 27.2 percent of the hospitals surveyed for this study confirmed that hospitals and manufacturers did enter into agreements to exploit consumers. However, a high 72.8 percent of hospitals

¹⁰⁸ Supra n 10

¹⁰⁹ Ibid

denied knowledge of such practices. Of those respondents who answered in the affirmative, 41.3 percent believed that such practices existed to quite some extent.

Figure 3.5: Hospitals and Manufacturers enter into agreements to exploit consumers-perceptions of hospitals

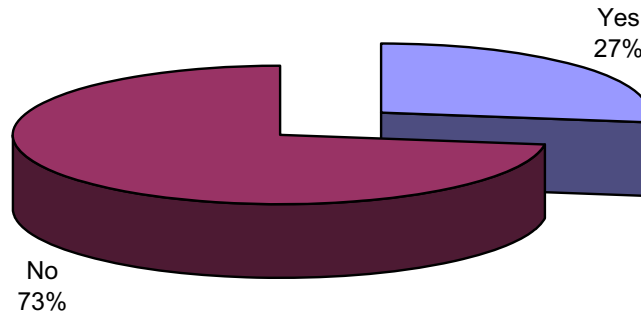
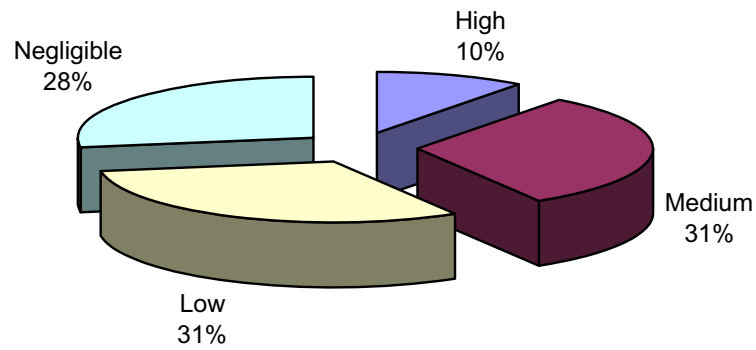


Figure 3.6: Extent of collusive agreements between hospitals and drug manufacturers



Our survey of doctors indicated that 19.5 percent of the physicians surveyed believed that hospitals and drug manufacturing companies entered into agreements to exploit consumers, with a high 51.1 percent of respondents unable to express an opinion on the matter. Of those who responded in the affirmative, 61.5 percent felt that it was quite a prevalent practice in the health sector.

Hidden costs, which is an issue in many hospitals is also anti-competitive in nature as the consumer pays more than warranted.

Tied Selling

A particular anti-competitive practice, common to all three of the aforementioned components of the health delivery system is tied selling. It basically means restricting choice of consumers by a provider of goods or services, in some other goods or services which may or may not be related. Tied selling occurs normally when there is monopolistic dominance or general scarcity in the market for some goods or services. However, it can also occur even otherwise if the market players act in collusion and all the players force such tied selling.

Overall, tied selling of medicines was not found to be a major problem as only about 15 percent of consumers surveyed claimed that they have been asked to buy medicines from a particular shop. However, in some cities the situation seems to be against the trend. On an average, those visiting private doctors or private hospitals reported a higher incidence of tied-selling of medicine. This was, however, not reflected in the responses of service providers who indicated that such practices may be equally prevalent.

Nearly half of the people who were asked to buy medicines from a particular medicine shop found prices to be reasonable there. However, this was not enough a reason to buy medicines from there and people mostly bought from there to follow doctor's advice or not to annoy him/her. Interestingly, less than two percent of the consumers could go against the advice of the doctors and buy the medicines from some other shop. It should also be mentioned here that more than half of these people thought that the issue here was of better or genuine medicines and only about 36

percent of them thought that their doctors advice was motivated by profit considerations.

The perceptions of consumer-oriented NGOs, however, differ substantially from the impressions consumers seem to have on the incidence of tied selling in the medical profession. In respect of the four cities of Delhi, Mumbai, Kolkata, Chennai, a high percentage of respondents, 54.9 percent claimed knowledge that doctors suggested buying medicines from a particular shop. They attributed the usual adherence to the recommendations given by the doctor to the implicit trust patients reposed in their doctor. Although a greater percentage (43.9%) considered tied selling to be expressive of the doctor's concern to ensure safe and reliable medicines, a high percentage of 31.6 percent of NGOs believed tied selling engaged in by doctors were motivated by profit considerations.

Figure 3.7: Motives behind tied selling of medicines-NGO perceptions

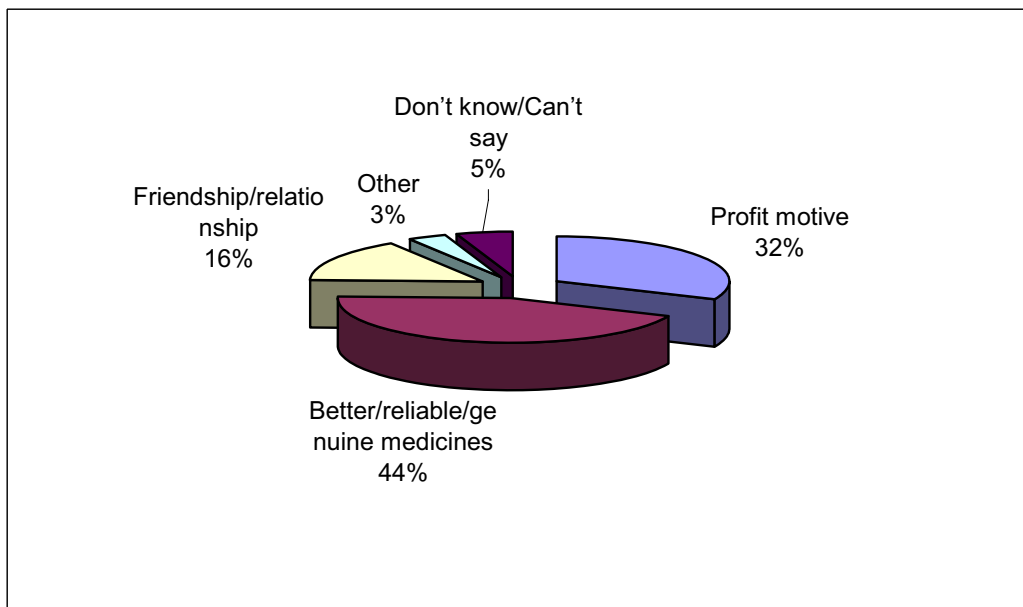
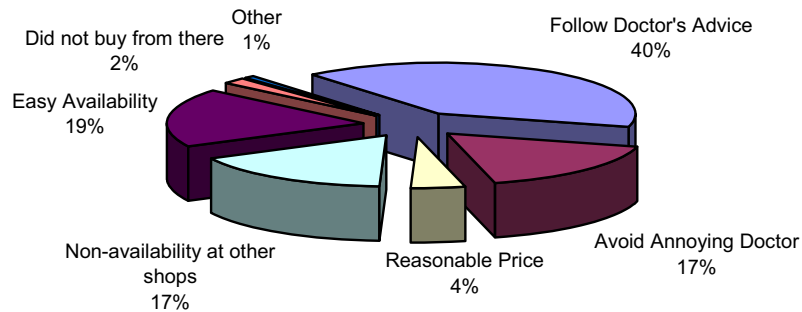


Figure 3.8: Reasons for Accepting Tied-selling of Medicines - Consumers



When doctors were asked about tied-selling of medicines, only 28.6 percent admitted that they ever resorted to such practices. And among them, none admitted to being motivated by profit considerations, 92.1 per cent asserting that they do it to ensure genuine and reliable medicines for their patients. When they were asked about whether other doctors gave such specific instructions, 52.6 percent responded in affirmative and 19.4 percent of them thought that the motive behind others resorting to such a practice was profit or commission considerations.

In our survey of hospitals, only 33 percent of respondents would admit to engaging in tied selling and among these respondents, 70.6 percent asserted that their reason for doing so was ensuring reliable and genuine medicines. Interestingly enough, only 44.1 percent of respondents believed that ensuring genuine and reliable medicines was the reason prompting tied selling in other hospitals. 26.5 percent attributed tied selling by their peers to profit making considerations.

49.6 percent of pharmacists surveyed admitted to having tie-ups with doctors and hospital; a small percentage of 19.5 percent of pharmacists denied the existence of such a practice. It may be noted in this context that there have been several media reports on the issue, including one investigative reporting by tehelka.com.

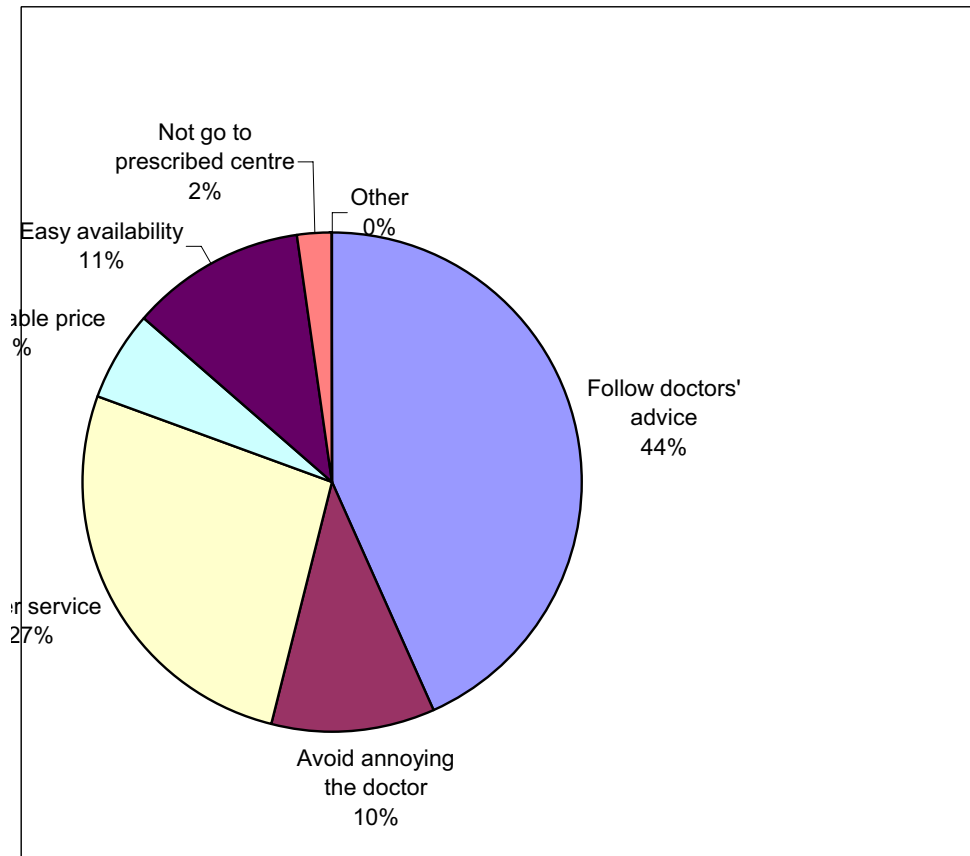
Recently, some pharmaceutical companies have entered into hospital business as well. Some of them are also getting into the business of retailing of medicines. It has also been reported that the chemists' association is forming a corporate entity in response to these plans. All these can have serious competition concerns.

Tied Selling of Diagnostic Tests

In our sample of respondents, slightly more than half of the people were asked to undergo some diagnostic test. Among these people, about half were instructed by the doctors to undergo the test at a particular laboratory. As with the medicines, people visiting private doctors or private clinics reported higher incidence of tied-selling of diagnostic tests.

Among the people who went to the prescribed laboratory, more than half went simply to follow doctor's advice or not to annoy the doctor. A quarter of them cited better and reliable service as the reason. A section of these people of course might have been influenced by their doctors to think so. Slightly more than five percent said the charge being reasonable was the reason, while for about 11 percent it was easy accessibility. Just about two percent of the people went against the advice of the doctor and got the testing done from a different laboratory.

Figure: 3.9: Reasons for Accepting Tied-selling of Diagnostic Tests - Consumers



It is, however, interesting to note that though about 35 percent of people thought that profit motive on the part of the doctors could be the reason for prescribing a particular test centre, an overwhelming 55 percent thought doctors advised so to ensure reliable services. It is quite surprising to see that a higher percentage of consumers than the service providers think that tied-selling of diagnostic testing is done to ensure reliable testing. Interestingly, about 43 percent of all the people interviewed thought tied selling practices by doctors are not ethical or justified. A high 30 percent could not give their opinion on this, while about 21 percent did not have any problem with such practices.

The survey shows that the people with higher income have relatively less problems with such practices. This may be due to the fact that price differentials have less significance for richer people and easy availability of the goods and services are important for them. They might also feel that paying slightly more may be worthwhile if the doctors have more confidence in a particular shop or a test laboratory.

Table 3.3: Views on Tied-selling by Income Groups

	Lower	Lower middle	Upper middle	Higher
Ethical & Justified	19	18.56	19.89	45
Unethical & Unjust	44.67	46.22	53.89	28.5
Not sure	36	33.89	26.22	21.5

Consumer oriented NGOs were also surveyed on this matter of tied selling of diagnostic tests. 75.5 percent of respondents believed that doctors ask their patients to go to a particular centre for diagnostic testing and cited that the primary reason as to why patients adhered to the recommendations given by their doctors was the implicit trust patients repose in their physicians. While a higher percentage of NGOs suggested that the doctors were motivated to make such recommendations in their concern to guide their patients to centres that provided reliable services, 27.3 percent of the respondents attributed these recommendations to profit-making considerations.

Regarding tied-selling of diagnostic tests, about 92.8 percent of doctors surveyed admitted that they suggested that their patients undergo diagnostic tests of which 56.7 percent recommended their patients to go for diagnostic testing at a particular centre. A high 93.1 percent of them argued that it was important to do so because of reliable testing services. Only 2.8 percent divulged that tied selling occurred for the purpose of garnering profits. More than half of them thought that other doctors/clinics do resort to such practices. However, in this context, a much higher, 20.2 percent of the respondents thought profit or commission consideration was the main motive, though more than half held the view that reliable service was the main motive. About 55 percent of doctors surveyed believed that such practices were justified and ethical, while a close 44 percent thought otherwise.

One form of anti-competitive practice (similar to full line forcing) which may be adopted by medical professionals is suggesting more tests than necessary which may be indicative of a profit arrangement scheme between doctors and diagnostic centres which breaches the basic competition principle of making available to consumers the best possible goods and services at the lowest possible prices. 30.8 percent of doctors surveyed categorically denied that medical professionals ever recommend more tests than strictly necessary while an almost equal, but slightly higher percentage, 33.1

percent of respondents responded in the affirmative to the question as to whether or not doctors recommend more tests than necessary at times. In contrast, a much higher percentage of 61.8 percent of the NGOs surveyed asserted that doctors insist on more tests than necessary and half of these respondents stressed that they believed this practice to be unethical.

That tied selling of diagnostic testing is prevalent in hospitals as well, is evident from 95.1 percent of hospitals surveyed mentioning that they recommend their patients to go for diagnostic testing of some sort, of which 46.9 percent admitted that they suggested that their patients undergo the tests from a particular centre. 73.9 of these respondents cited reliability of services as their motivations behind such recommendations. As to why other hospitals recommend that their patients visit a particular diagnostic centre, 76.5 percent of respondents asserted that such tied selling is prevalent, however, a high percentage of 57.3 percent attributed reliable services being the cause behind such recommendations for other hospitals as well. However, 25.3 percent of these respondents attributed tied selling by other hospitals to profit-making considerations. 39.8 percent of all hospitals surveyed felt that the practice of tied selling of both medicines and diagnostic testing is unethical.