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Dealing With Anti-Competitive Practices in the Indian Pharmaceuticals and the Health Delivery Sector

It is an undeniable fact that access to healthcare is one of the most basic needs and an inviolable right of every human being. The right to health has been recognised in a number of international legal instruments. Globally, the drug sector has been known for practices thwarting the spirit of competition and regulation. Hence, the role of the competition authority is very crucial in placing appropriate restraints. In India, too, there are constitutional commitments, providing access to healthcare.

However, despite tall claims only 35 percent of the people in India have access to essential medicines. Several factors are responsible for such deprivation — malpractices in the market as well as anti-competitive conduct in the pharmaceutical industry and the health delivery system.

Given the grim scenario, CUTS International conducted a study in 2005-06 on “Options for Using Competition Law/ Policy Tools in Dealing with Anti-competitive Practices in Pharmaceuticals and the Health Delivery System”, which was supported by the World Health Organisation (WHO) and the Ministry of Health and Family Welfare, Government of India. The overall objectives of the study were to: identify competition concerns in the pharmaceutical sector and health delivery system; examine the scope of competition policy and law in dealing with such concerns; and suggest an implementation strategy to enhance access to medicines efficiency of health delivery systems.

This briefing paper addresses the twin objectives of highlighting the study findings as well as examining legal and policy options to effectively curb anti-competitive practices in the health sector in the country.

I. Introduction

The pharmaceutical industry is currently acknowledged as one of the leading industries in India. In fact, India is ranked among the top 15 drug manufacturing countries in the world. However, the Indian pharmaceutical sector is in a state of flux in the face of the sweeping changes in the patent regime and the increasingly de-regulated environment. Especially threatened in this new scenario is access to medicines for the poor. Moreover, though India has a vast health delivery system in place it is not comprehensive enough to serve a population of over one billion. Access to medicines and healthcare has five important aspects:

- Availability of supply;
- Price;
- Quality;
- Ability to pay; and
- Access to proper and affordable consultations.

All these aspects are adversely affected by a number of factors, which range from poverty and poor infrastructure

to corruption, market malpractices, and lack of awareness. Market malpractices in general, and anti-competitive conduct in the pharmaceutical industry and health delivery system, in particular have serious implications for access to healthcare.

Further exacerbating the situation are market distortions and skewed competition norms, unique to the pharmaceutical industry, with particular reference to market concentration, barriers to price competition, and lack of freedom in consumer choice (patients are guided by the advice of doctors and pharmacists). The health delivery system is also characterised by market failure uncommon in other markets, that is, consumers are mostly not involved in decision making regarding consumption, which in this case consists of medicines and healthcare facilities.

Anti-competitive practices in the pharmaceutical sector and the health delivery system include, amongst others, price fixing, abuse of dominance, collusive agreements, and tied selling. Even practices such as kickbacks to

doctors and pharmacists may be deemed as anti-competitive, as they result in depriving patients of the best possible medicines and services at the lowest possible prices. The primary effect of anti-competitive practices on the health sector is that medicines and services are rendered costlier. In order to deal with anti-competitive practices in the pharmaceutical industry and the health delivery system, there are multiple legal and policy options such as competition law, patent law and drug price control, which may be utilised effectively. Competition concerns relating to the pharmaceutical industry and healthcare delivery system are discussed in the following section. A discussion of legal and policy options is provided in Section III. The last section provides concluding remarks.

II. Competition Concerns

It is to be noted that a number of anti-competitive practices pervade the pharmaceutical industry worldwide, including India. An issue of vital importance, however, is that consumers of formulations are very often not the decision-makers. They are, for the most part, guided by instructions from doctors and pharmacists. The significant role assumed by the doctors and pharmacists in influencing drug sales leads to manipulation of the system with drug companies seeking to exploit this influence, more often than not. Such practices result in patients being misled into purchasing more expensive medicines, or the prescribing of irrational (or combinations of) drugs, which may lead to medical complications, sometimes even causing death. This distorted guidance on the part of the doctor deprives patients from availing of the best possible healthcare.

Empowering consumers is a task fraught with difficulties, since medicine is a highly specialised field in which miscalculations in the decision making process may lead to severe adverse and sometimes even irreversible effects on health. Anti-competitive practices in the pharmaceutical sector may be categorised into primarily three classes: breaches related to intellectual property rights (IPRs); abuse of competition norms arising from mergers and acquisitions (M&As); and collusive and other anti-competitive practices.

IPRs Related Anti-competitive Practices

In principle, patents confer monopoly status to pharmaceutical companies; as patent by its 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. However, since 2005 onwards when India made the transition to the product patent regime, any patented product entering the market is being marketed by a monopolist.

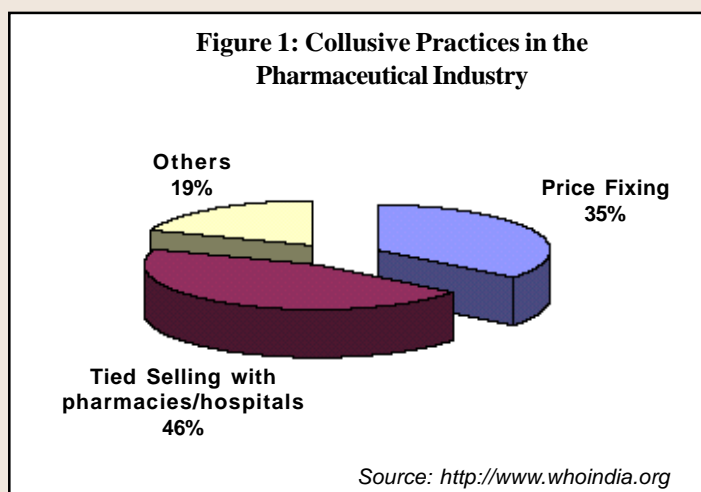
This means that in the new patent regime, abuse of dominance, which was almost non-existent earlier may become quite frequent. Consider the Novartis case which involves IPR-related issues in the health sector. Novartis filed an application for patenting its cancer drug Gleevac, used for treating leukaemia, which was turned down by the India Government. Novartis filed a case in the Madras High Court challenging the decision. The treatment with Gleevac costs Rs 1,20,000 per month for a patient as compared to Rs 8,000 per month with its generics. Those who have supported the decision of the Indian Government have argued that India is a source of cheap medicines for developing countries and if Novartis wins the case it will lead to drying up of a source of affordable medicines to these countries. Novartis has lost the case.

Collusive Practices in the Pharmaceutical Industry

In practice, collusive activities (see Figure 1) can range from cartelisation to bid-rigging. 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 (Vitamins Cartel) had been in existence in the country for quite a long time.

Increasing Concentration

As of now, the Indian pharmaceuticals industry is highly fragmented though it is expected that the coming years will see intense consolidation activities. Moreover, M&As are not necessarily anti-competitive and may lead to creation of efficiencies. However, the concern is whether the M&As or the joint ventures will enable parties to achieve or strengthen a dominant position in markets in which they compete and whether that may



increase the prices of the products. For example, such transactions may eliminate a significant direct competitor in a relevant therapeutic category, particularly where there are a few substitutes and new entry is difficult. Due to technological and regulatory impediments to entry, this is often the case in many pharmaceutical markets.

Anti-competitive Practices in the Health Delivery System

We now examine the anti-competitive practices which are widespread in the health delivery system, which includes doctors, hospitals, diagnostic laboratories, and pharmacists. Given the anti-competitive practices in health delivery system, only 35 percent of Indians can access essential medicines. There are a number of factors, which would account for the lack of access to healthcare services and medicine. Anti-competitive practices are classified by type and the involved agent and are discussed below.

Incentives: Giving incentives to doctors and pharmacists is one practice carried out by pharmaceutical companies, which blatantly violates free and fair competition. This may be motivated by a desire to create a large 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. Many competition legislations around the world consider 'incentives' as unfair trade practices (UTPs); and therefore prohibiting them.

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, the drug for ADD. By expanding the use of the drug that has been responsible for millions of children misdiagnosed with ADD, Novartis has encouraged anti-competitive practices.

Prescription: The most significant unethical practices engaged in by doctors are prescriptions which are motivated by the kickbacks received from pharmaceutical companies. Even if not influenced by incentives, doctors may continue prescribing a particular drug found to be effective, and do not bother to find out if there are existing less expensive alternatives.

Commissions: Another practice, which is rather prevalent among doctors, is to provide referrals that are motivated by commission. Doctors are quite often paid commission for referring the patient for further treatment or to any particular diagnostic centre, pharmacist, or hospital.

Diagnostic Laboratories and Pharmacists: The anti-competitive practices most prominently engaged in by pharmacists are reflective of collusive behaviour. It may be concluded that pharmacy owners are banded together to form a huge cartel in the guise of a trade association named as the All India Organisation of Chemists and Druggists (AIOCD). The AICOD is known to launch boycotts against companies to grab higher profit margins, which is ultimately passed on to the consumers.

Hospitals: Hospitals are an important part of the health delivery system. However, not much is known about their practices though random analysis reveals that they are known to exploit consumers, and enter into agreements with drug manufacturers.

A case that was brought before 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 above the market price.

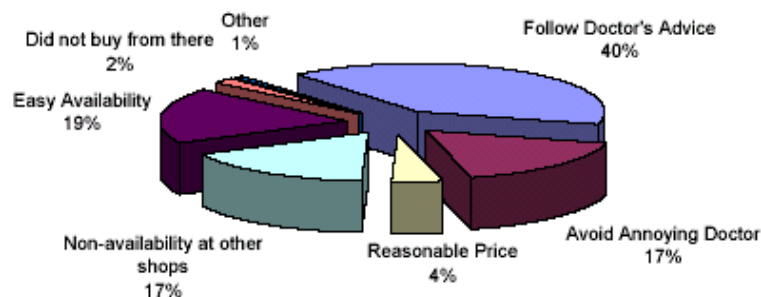
A peculiar anti-competitive practice, common to all three of the aforementioned components of the health delivery system, is tied-selling (see Figure 2). It basically means restriction of the choice of consumers, by a provider of a certain good or service, in the purchase of some other goods or services which may or may not be related. For instance, a doctor tying his services to the purchase of medicine from a particular medicine shop or 'strongly recommending' tests at a particular diagnostic centre in lieu of some commission is a case of tied-selling.

Box 1: Boycott or Joint Refusal

In 1984, the Retail and Dispensing Chemists Association, Bombay, was brought before the Monopolies and Restrictive Trade Practices Commission (MRTPC) after it directed all wholesalers and retailers to boycott a company's product till the Association's demands were met by the company. The MRTPC observed that the impact of the chemists' boycott could not be considered negligible. The boycott represented an attempt to deny the consumers certain products to which they were accustomed. The MRTPC then passed a 'cease and desist' order.

<http://www.cuts-international.org/articles-jan-june05.htm>
(RTP Enquiry No. 10/1984)

Figure 2: Reasons for Accepting Tied-Selling of Medicines: Consumer's Views



Source: <http://www.whoindia.org>

delivery systems. Hospitals are virtually ungoverned in this respect. In some states, there are laws that provide for mandatory registration and technical standards for clinical establishments including hospitals, nursing homes, or diagnostic centres. However, the coverage is not comprehensive. With the hospital industry growing, this gap needs to be addressed.

The new Indian Pharmaceutical Policy, 2002, has focused on liberalisation by further reducing the number of drugs subject to price control and opening up the

market to foreign investment.

III. Legal and Policy Options

There exist multiple legal and policy options, which may be utilised to deal with anti-competitive practices in the pharmaceutical industry and the health delivery system. These options have been considered in the light of facilitating access to medicines and healthcare.

Using competition law is an obvious legal remedy to deal with anti-competitive practices in the pharmaceutical industry and health delivery system. The key element in successfully enforcing the provisions of competition law is building the capacity of the competition agencies.

Competition law apart, patent law and drug price control are crucial for efficacious elimination of competition violations in the pharmaceutical industry. The Patent (Amendments) Act, 2005 introduces product patents in India, invalidating Section 5 of the Indian Patent Act, which granted only process patents for food, medicines and other drug substances. Under the Patent (Amendments) Act, 2005, monopoly status is awarded to patent-holders. The Indian Patent (Amendment) Act, 2005, also provides compulsory licensing under Section 84 and 90. Generally, three years after a patent is granted (sealed), any interested party can allege that the invention is not reasonably available to the public and can request the grant of a compulsory licence.

Price control is a tool that is used in a situation when maintaining a competitive market is extremely difficult. India has been following a price control regime for pharmaceutical products since the 1960s. However, there has been substantial decontrol in this regard since the 1990s, with the effect that prices of many medicines have seen an unprecedented rise. Under the Drug Price Control Order (DPCO) 1995, only 74 drugs are under price control. The DPCO is to be succeeded by the National Pharmaceutical Policy of 2002, which contains several important policy changes.

Competition law is an effective regulatory mechanism for addressing anti-competitive conduct in the health

IV. Recommendations

The section offers some vital suggestions and recommendations for improvement in the healthcare and hospital delivery system.

Promoting Generic Competition

Pharmaceutical companies often give incentives to doctors to push their brands of medicine, which may be more expensive than other alternatives available in the market. This vitiates the competition principle of “best possible goods and services at the least possible prices”. The doctor-drug manufacturer nexus is to be viewed in the light of near complete dependence of patients on the doctors for information relating to drug purchase. In order to deal with this unholy nexus, there is a need to promote generic drugs. This promotion may be done by

Box 2: Applying the Indian Competition Law

The three focal areas of anti-competitive conduct covered by the Indian Competition Act, 2002, as amended by The Competition (Amendment) Act, 2007, relate to: anti-competitive agreements; abuse of dominance; and combinations – all three of which give rise to competition concerns in the pharmaceutical industry and the health delivery system. The specific anti-competitive practices of the pharmaceutical system and the health delivery system, covered by the Act are collusive agreements including cartels, tied-selling, exclusive supply agreements, exclusive distribution agreements, refusal to deal, and resale price maintenance.

The Competition Act, 2002, as amended by The Competition (Amendment) Act, 2007 prohibits the abuse of dominance and, therefore, if pharmaceutical companies do engage in overpricing patented products or are unreasonable with respect to licensing terms and so on, the competition law may be resorted to for redressal.

de-branding prescriptions for essential generic medicines. However, there are strong legitimate arguments against this proposition, which are beyond the scope of this paper. It is, therefore, recommended that only a selected number of most commonly used medicines be brought under the 'de-branding of prescriptions' scheme on an experimental basis.

Dealing with IPR Related Issue

Patent grants monopoly rights to patent holders. In the pharmaceutical industry, such patents are granted to pharmaceutical companies and in a number of cases are susceptible to abuse, especially in the form of excessive pricing. Compulsory licensing is an effective way to deal with such abuse of monopoly rights. A patent-holder's refusal to allow a licence may constitute an abuse of patent rights when it causes undue harm to domestic industry. In this case, an interested party may request a grant of compulsory licence or even a cancellation of the patent right. Article 8A of the Trade Related Intellectual Property Rights (TRIPS) Agreement and Article 5A of the Paris Convention deal with the abuse of patent right by the patentees. These articles provide suitable measures that can be taken by the government to prevent such abuse.

The experience in India's previous product patent regime indicates that the practical aspect of licence issuance needs to be given due attention if there is to be any likelihood of actualising the grant of compulsory licences. It is recommended that it would be more appropriate to give the competition authority the responsibility of granting compulsory licences in consultation with the patent office, rather than the other way around. This recommendation is in agreement with the proposed policy of mandatory price negotiations of patented drugs before the grant of marketing approval. Besides, bureaucratic delays in granting compulsory licenses in India should also be removed. It is recommended that while framing guidelines in this respect, India may look at the experiences of other countries, which follow similar practices, such as Canada, France, Germany, Italy, Japan, and the UK.

The IPR related agreements have been exempted in the Indian Competition Act, 2002, as amended by The Competition (Amendment) Act, 2007, even if they contain anti-competitive provisions which are reasonable, without defining what is reasonable. This will create confusion. Moreover, some of the provisions can be purely anti-competitive and cannot be justified in the interests of promoting innovation and hence should not be exempted even with a rider of reasonableness. Abuse of dominant positions relating to IPRs like monopoly pricing, exclusive dealing, tied sales, restrictions on end users, etc., has also not been covered by Indian

Competition Act, 2002, as amended by The Competition (Amendment) Act, 2007.

Checking Collusive Activities

Collusive activities among Indian manufacturers of pharmaceuticals have not yet been discovered. However, their prevalence cannot be ruled out. Pharmacies engage in collusive practices in India to ensure higher trade margins. The government has created deterrence mechanisms, though these have limitations and need to be re-examined. There exists a strong need to eliminate collusive practices by pharmacies to ensure growth of the industry, including that of ensuring a fair deal for consumers.

Controlling Tied-Selling

Tied-selling in the health delivery system, although anti-competitive in effect, may partly be driven by safety considerations as well, rather than profit concerns only. Although there is regulatory framework to ensure genuine medicines in the market, there is significant scope for improvement in its enforcement. In the area of diagnostic testing, however, the regulatory framework is almost non-existent. It is recommended that regulatory authorities at the state level should be properly empowered to ensure standards of medicines and services offered at the diagnostic laboratories. Consumer forums ought to be actively involved to ensure that patients are not exploited.

Regulating Health Delivery Systems

Given the predominance of the private sector in the health delivery system and the absence of regulation of the functioning of private hospitals, nursing homes and other medical care establishments, some measures for licensing and regulation need to be taken. Hospital accreditation is one method which may be used to regulate hospital conduct. There is also need for a programme of stricter licensing for medical practitioners. Bridging the huge information gap, which exists between consumers and health services providers, may also assist in stemming the incidence of anti-competitive practices in the health delivery system.

Box 3: Questions before Regulators

There are many questions for regulators to consider:

- Should the manufacturers also be allowed to engage in collective bargaining with the pharmacists?
- Should there be a trade margin fixation regime?
- Should there be a negotiated settlement in the short run?

These options need to be considered in light of existing law, the practicalities involved and long-term implications.

Health Insurance

The most pernicious effect of nearly all anti-competitive practices in the health sector is the resulting hike in the prices of medicines and health services. Health insurance is one way to lessen the impact of high prices on the consumer. However, health insurance itself causes market distortion in the health sector. Ultimately, patients end up bearing the cost of market inefficiencies. Health insurance thus has a multi-dimensional impact. In this regard, it is further recommended that the government should explore the possibility of enhancing the coverage and effectiveness of National Illness Assistance Fund for families below the poverty line (BPL). It is further suggested that lessons may be drawn from other countries, where health coverage through insurance is more prevalent than in India.

Promoting Innovation

With the transition of India to the product patent regime, it is imperative for our domestic pharmaceutical industry to accelerate its efforts in research and development (R&D). This paper emphasises that total price decontrol as suggested by industry representatives, is unnecessary to promote R&D and suggests a carrot and stick approach to encourage R&D by companies. There has to be incentives and disincentives directly linked with R&D efforts. Furthermore, there is a need to not only focus on private R&D, but also to actively promote public R&D. This report also advocates that Indian companies should file as many patents for herbal medicine as they can. The Indian Government should actively support such initiatives in whichever way possible.

Creating Awareness

The implementation of many of the aforementioned policies and measures will require the involvement of all stakeholder groups. It is suggested that there should be capacity building of all involved groups through awareness campaigns on all of the aforementioned issues and other means as well. The Central Government, State Governments, and all interested non-governmental organisations (NGOs) need to be involved in creating awareness. The Clinical Establishments (Registration and Regulation Bill), 2007, has been introduced in the Indian Parliament, which proposes for the creation of a National Council for Regulation and Standardisation of Clinical Establishments. Once enacted, it can change the scenario relating to availability, accessibility, quality of service provided in the Indian health sector.

V. Conclusion

Given the peculiarity of the market, ensuring competition is easier said than done. The Indian Competition Act, 2002, as amended by The Competition (Amendment) Act, 2007, is better equipped than the MRTP Act to deal with the anti-competitive practices prevalent in the health sector. Currently, the regulatory regime has been quite harsh on drug manufacturers, but extremely soft on two other groups of important players – the doctors and pharmacists. This situation needs to be given due consideration by the relevant authorities.

This Briefing Paper is researched and written by **Souvik Chatterjee, Nupur Anchlia** and **Smita John** of and for CUTS Centre for Competition, Investment & Economic Regulation (CUTS C-CIER) based on a Research Study entitled, 'Options for Using Competition Law/ Policy Tools in Dealing with Anticompetitive Practices in the Pharmaceutical Industry in the Health Delivery System' conducted by CUTS with the support of the World Health Organisation and the Ministry of Health and Family Welfare, Government of India.

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