PHARMACEUTICAL SECTOR AND THE COMPETITION LAW: AN INTERFACE

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ABSTRACT

The regulatory laws regarding the pharmaceutical sector aim to promote good quality of drugs but at affordable prices and at the same time aims to promote the innovation in the sector. Question of availability and affordability of drugs is at the core of any public discussion around this sector. But innovation and development of new drug is again most important one. Keeping balance between innovation and affordability and availability of drugs, the Indian regulatory laws have built a robust network, right from preparing drug formulations to issuing intellectual property right to bring it into the market. But still there are lacunas which come under the ambit of some special kind of laws. Competition law is such which sees this healthcare sector from market point of view with an aim to keep checks market chain, pricing, monopoly etc. In this paper the author has outlined the interface between pharmaceutical sector and the competition law.

The Indian pharmaceutical sector is one of the leading sectors contributing to the economic growth of the country. The uniqueness of this industry lies in its importance from both consumer/patient and market perspective. On one hand, the pharma industry is the backbone to the healthcare system; on the other hand, it heavily contributes to the nation's economy. The pharma industry of India is projected to grow to US$100 billion, whereas the medical equipment and device market is anticipated to grow US$ 25 billion by 2025. In FY20, the export from India counts at US$ 16.3 billion which includes bulk drugs, intermediates, surgical, drug formulations, biologicals, Ayush and Ayurveda. The domestic turnover of the pharma industry touched Rs 1.4 lakh crore (US$ 20.03 billion) in 2019 from Rs 129,015 crore (US$ 18.12 billion) in 2018.[1]The two aspects, dynamic healthcare and the economic growth make the industry to some extent sensitive and seek the support of a sound legal system. Being a sensitive sector, the pharma sector is protected by numerous laws. Each step from the R&D to formulations to making and production of a drug, the entire sequence is being regulated and protected because of its sensitiveness and uniqueness[2] of the industry.

The first concern which is primary to the industry is to innovate and develop new drugs. This is called the Research and Development "R&D". The "R&D" branch is the top most necessity of any pharma company. The big pharma companies in the west spend huge money on innovation and its protection. The pharmaceutical industry is often dependent on high research and development costs in order to produce a viable product, and sometimes the performance rate is relatively low for any given research and development project. Of 10,000 molecules that are patented and cross the stage of basic testing, only roughly one is sold commercially, and the current expense of marketing success is valued at over USD 2.5 billion. In the absence of any security, the industrial development of intellectual property is open to anyone once produced. Due to the related costs and threats, and the fact that the pharmaceutical firm creating the R&D risk is funded almost exclusively, the manufacturer must be given ample motivation to participate mainly in R&D operations.[3] Once the drug is innovated, the second step is to

[1]Indian Pharmaceutical Industry Report (November 2020) available at Indian Brand Equity Foundation https://www.ibef.org/industry/pharmaceutical-india.aspx

[2] There are couple of reasons which make the pharmaceutical sector a unique one. In the pharma sector the end user do not make any active choice in the medicines they purchase except for the over-the-counter (OTC) segment. The physician made the choice on behalf of the consumer-patient in his/her best interests. Secondly, in other sectors, even if a consumer does not make any choice or the choice he/she make is beyond his/her means, the consequence will not be that grave, which may be in the pharma sector. Cost of R&D is another issue which also make it unique.

[3]Shamim S. Mondal and ViswanathPingali, *Competition Law and the Pharmaceutical Sector in India* P.8, Working Paper 2015-11-02 Indian Institute of Ahmedabad.

protect it. The new drug can be protected under the intellectual property laws "IP" laws. The IP laws grant a legitimate monopoly to the company which innovates the drug for a certain time and the entire idea of this protection is to reward and promote the innovation.

The availability and the affordability of medicines play significant role among the industry, law and life. To keep a fine balance between innovation and the availability and affordability is a huge task which is being played by various regulatory bodies. If we look at the pharma sector, the regulatory system works at the two levels: one is licensing and the second is pricing. Licensing is a core activity of the industry which is directly related to innovation and patent laws. The pricing is another important issue which directly hits upon consumer/patient pocket, is being taken care by various laws and regulations. There are a large variety of practices which influence the pharmaceutical sector generally, for example: drug procurement by the government, price regulation, encouragement by the patent laws for innovation and inventions, data protection, drug promotion, regulating the drug advertisements, trademarks etc. To regulate all these practices, there are variety of laws and regulations.

Competition law which regulates the anti-competitive practices, prevent the abuse of dominant position and regulates the merger and acquisition plays an important role to prevent the pharma industry to exploit the consumer. The modern competition law in India not only breaks the monopolies but also promotes competition in the market. The competition law through the Competition commission of India (CCI) keeps a check on the anti-competitive practices carried out in the market by preventing anti-competitive agreements, abuse of dominant position by any entity and affecting the competition by merger and acquisition. The CCI is an independently statutory body which regulates the competition related matters in the market.

Pharmaceutical Regulatory Laws in India

As we have discussed in the above para, that the pharma industry is influenced by various practices. Some of the practices are illegal per se and some are to fulfil certain conditions in order to become capable of entering into the market. Here is a list of some important legislations and rules which oversees the drugs right from the production to its consumption.

- Drugs and Cosmetics Act 1940 (DCA), the Drugs and Cosmetics Rules 1945 (DCA Rules) and the Drugs (Control) Act 1950, these laws regulate the import, manufacturing and distribution of pharmaceutical products. The schedule M of the Act specifies the criteria for the basic installation. It laid down the conditions to set up a plant, the

required area for installation, material and equipment to be used. Schedule T of the Act laid down specifications for manufacturing of Ayurvedic, siddha and Unani medicines. Schedule Y of the Drugs and Cosmetics Act oversees the requirements to run clinical trials of drugs.

- The Pharmacy Act 1948 and the Pharmacy Practice Regulations 2015 (the Pharmacy Regulations): This Act regulates the pharmacy profession in India. It prescribes the conditions and qualifications to professionally run a Pharmacy. Under this Act, the provisions are given to set up the Central pharmacy Council and the State Pharmacy councils under the supervision of Central and the State governments respectively.

- The Drugs and Magic Remedies (Objectionable Advertisements) Act 1954: This Act provides rules to control the advertisement of drugs in India. It also prohibits misleading advertisements and advertisement claims that a drug possesses any magical quality.

- The Medicinal and Toilet Preparations Act 1955: This Act levies an excise duty on the drugs and medicinal preparations that contain alcohol, narcotic drugs or narcotics.

- The Drugs Price Control Order (DPCO), 1995, the Drugs (Price Control) Order 2013[4] (DPCO): The DPCOs are orders promulgated by the Central government under the Essential Commodities Act 1955 to regulate the prices and listing of essential medicines.[5] These orders laid down the list of price controlled drugs, the procedure how the drug prices are fixed, the method to implement controlled price medicines and it

[4] With a key goal to ensure the availability and affordability of "essential medicines" at fair and affordable price, the Government of India has informed in the 2012 National Pharmaceutical Pricing Policies (NPPP) to achieve its primary purpose. This has been achieved in order to ensure that the pharmaceutical sector provides ample resources for growth and competition, so that the pharmaceutical industry can expand overall. In 2013, DPCO was subsequently released to replace the previous DPCO in the light of the NPPP. Previously, only 74 bulk drug products were price-regulated, while the new DPCO controls the prices of up to 348 medications. It provides for the prices of 348 medicines that come under NLEM (National List of Essential Medicines) 2011 to be controlled by the NPPP. The first controls medication prices based on production costs as set down by the respective producer, whilst the latter estimates prices for an overall market share of all drug brands above 1 percent.

[5] The price control was first time introduced in the country after the Chines aggression with the promulgation of the Drugs (Display of prices) order 1962 and the Drug control of prices order 1963. These orders were promulgated under the Defence of India Act. There after two more DPCO were promulgated under the Essential Commodities Act 1955 in 1966 and 1970. Thereafter under the drug policy of 1978 and 1986 two more DPCO were promulgated in the year 1979 and 1987 respectively. Later on the Drug Policy of 1994, executed through the DPCO 1995 in the context of liberalization of the economy. In the year 2002 FDI (Foreign Direct Investment) was brought in the pharma sector to enhance the liberalization more effectively. In view of this, a new Drug policy were brought in the year 2002 which was later on challenged in the Karnataka High Court. The 2002 policy was never implemented. In its absence the 1994 policy continued to play its role. Later on the Government felt the need to set up a new policy which was set up in the year 2012.

also provides the penalties in case of the contraventions of the order. The government has vested the powers in the National Pharmaceutical Pricing Authority (NPPA) to implement the provisions of the orders. It is to be noted that the price controls are applicable to the Schedule Formulation drugs (the drugs mentioned in Schedule I of the DPCO). The schedule can be located at the official website[6] of the National Pharmaceutical Pricing Authority. Only the authority has the power to revise the retail price once the drug is notified in the schedule. These scheduled formulations also include drugs from the 2015 National Registry of Essential Medicines, which includes an exhaustive list of essential drugs under regulatory supervision, as the name suggests. The Ministry of Health and Family Welfare (MOHFW) decides, by means of a consultation process, the medication to be included in the National List of Essential Medicines (NLEM). The consultation takes a few years (usually 3 years), and based on the World Health Organization's two year updates and changes to the Essential Medicines Model List. The "Non-scheduled formulations" are not subject to price control, that is, formulations not specified in Schedule I of the DPCO. However, the DPCO provides only up to 10percent rise in market prices of such formulations annually. In addition, in the event of unusual circumstances and in the public interest, the Government of India (GoI) shall be entitled to decide, for as long as it deems fit, the ceiling price or retail price of any medication, whether the drug is scheduled one or not.

Pharmaceutical Sector and the Competition Law

The competition Act 2002 came in the year 2003 after receiving the assent of President of India on 13th January 2003 by replacing a long standing monopolies preventive Act, MRTP 1969. The Act was amended in the year 2007 and then in the year 2012. Some of the substantive provisions of the Act came into force in the year 2009.[7] To understand the essence of the Act, we can broadly categorize it into two parts. One part is covered with substantive provisions and its execution, the second significant part talks about awareness. Along with the execution and implementation of various substantive provisions, Act 2002 also provides advocacy provisions

[6] The schedule formulations are in the schedule which can be seen at http://www.nppaindia.nic.in/wp-content/uploads/2018/12/DPCO2013_03082016.pdf

[7] On 15th of May, 2009, the Ministry of Corporate Affairs notified certain sections of the Competition Act, 2002 by powers vested in it under section 1(2). Sections 3 and 4 are operational from the 20th day of May, 2009.

to disseminate the awareness about the subject among masses. Broadly there are four major objectives of this Act:[8]

1. Prevention of activities having adverse effect on the competition
2. Promoting and sustaining the competition in the market
3. Protection of the interests on the consumers
4. Ensuring the freedom of Trade

The Competition Act 2002 establishes a commission namely Competition Commission of India (CCI *hereinafter*). The CCI is the statutory body under the Act consisting of a chairman and two to six full time members. The commission perform its duties[9] through Director General (DG)[10] who conduct inquiries in case of any contravention of the provisions of the Act. The Competition Act 2002 looks into the following four issues which come under its domain.

a) Anti-competition agreements causing appreciable adverse effect (Section 3)[11]

b) Abuse of Dominant position (Sector 4)[12]

[8] The preamble of the Competition Act 2002 says: An Act to provide, keeping in view of the economic development of the country, for the establishment of a Commission to prevent practices having adverse effect on competition, to promote and sustain competition in markets, to protect the interests of consumers and to ensure freedom of trade carried on by other participants in markets, in India, and for matters connected therewith or incidental thereto.

[9] Section 18 Competition Act 2002
Duties of Commission: Subject to the provisions of this Act, it shall be the duty of the Commission to eliminate practices having adverse effect on competition, promote and sustain competition, protect the interests of consumers and ensure freedom of trade carried on by other participants, in markets in India:
Provided that the Commission may, for the purpose of discharging its duties or performing its functions under this Act, enter into any memorandum or arrangement with the prior approval of the Central Government, with any agency of any foreign country

[10] Section 16 Competition Act 2002 talk about the appointment of the Director General for the purpose of assisting the commission in conducting the inquiries into contravention of the provisions of the Act and for performing other functions assigned to him/her as per the provisions of the Act.

[11] Section 3 of the Competition Act 2002 says No enterprise or association of enterprises or person or association of persons shall enter into any agreement in respect of production, supply, distribution, storage, acquisition or control of goods or provision of services, which causes or is likely to cause an appreciable adverse effect on competition within India.

[12] Section 4 of the Competition Act 2002: No enterprise or group shall abuse its dominant position.](2) There shall be an abuse of dominant position 4 [under sub-section (1),if an enterprise or a group].—-(a) directly or indirectly, imposes unfair or discriminatory—(i) condition in purchase or sale of goods or service; or (ii) price in purchase or sale (including predatory price) of goods or service.

c) Merger or in general sense combinations among enterprises (Section 5 and 6)[13]

d) Competition advocacy (Section 49)

The Commission has the power to conduct an investigation "on its own motion" or to obtain any information from or on behalf of any concerned / affected party made, by reference of central or state governments or by any other legislative bodies. After receiving information, the Commission can determine if there is no prima facie case exists, or exists and order the DG to perform an inquiry. After an inquiry is carried out, the DG may recommend whether an infringement case is made out as per the law or not. The Commission invites the suggestions or objections from the parties involved, following the receipt of the recommendations of the DG. Commission can either close the matter and give its decision after reviewing all the submissions or choose to carry out a further investigation, either with or by itself the DG. When Commission finds any violation of the Competition Act then it is empowered to cease the presumed anti-competitive activity and enforce a fine which does not surpass 10% of the total revenue of the last three financial years. In the event of merger or acquisitions, the CCI shall be empowered to provide notices of evidence to M&A parties, and it may perform an inquiry if it finds such action necessary following receipt of replies from the parties. The CCI can allow M&A to be carried out when its pro-competitive advantages are met or it may prohibit the M&A if it considers that it adversely affects the competition or the commission can also propose some changes. The Act also provides that the decisions of the commission are subject to appeal before Competition Appellate Tribunal (COMPAT) which was recently replaced by National Company Law Appellate Tribunal (NCLAT) in 2017.

When an alleged matter comes before the commission in contravention to section 3 and 4, it sees if a *prima facie* case exists, if the exists so, then the commission orders an investigation under section 26(1). In cases the prima facie case does not exist, and then the Commission closes the matter under Section 26(2) of the Act. If after an investigation, no case is made out,

[13] Section 5 of Competition Act 2002: The acquisition of one or more enterprises by one or more persons or merger or amalgamation of enterprises shall be a combination of such enterprises and persons or enterprises, if—(a) any acquisition where—(i) the parties to the acquisition, being the acquirer and the enterprise, whose control, shares, voting rights or assets have been acquired or are being acquired jointly have,— (A) either, in India, the assets of the value of more than rupees one thousand crores or turnover more than rupees three thousand crores; or (B) [in India or outside India, in aggregate, the assets of the value of more than five hundred million US dollars, including at least rupees five hundred crores in India, or turnover more than fifteen hundred million US dollars, Including at least rupees fifteen hundred crores in India.
Section 6 of the Competition Act 2002: No person or enterprise shall enter into a combination which causes or is likely to cause an appreciable adverse effect on competition within the relevant market in India and such a combination shall be void.

the Commission may close the matter under Section 26(6). In case of any contravention, the Commission will pass an order under Section 27 of the Act on the basis of that investigation. Sometimes, interim orders can also be issued under Section 33 of the Act. The following given figures are exemplifying the progress of the commission.

Numbers of orders passed by the CCI figure **1**					
Year	Orders passed under section 26(1) and (2) in prima facie cases	Orders passed under Section 26(6) after DG report	Orders under Section 27	Orders under Section 33	Total no of cases
2009-10	29	-	-	-	29
2010-11	116	8	1	18	143
2011-12	89	37	29	13	168
2012-13	83	15	17	4	119
2013-14	122	8	13	10	153
2014-15	114	2	20	8	144
2015-16	119	17	14	3	153
2016-17	167	4	7	1	179
2017-18	77	6	12	1	96
2018-19	67	24	21	3	113

Total	**981**	**122**	**135**	**61**	**1299**

*Source: Annual Report of CCI 2018-19

Anti-trust Matters noted by the commission as on 31st March 2019

figure **2**

Sector	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19	Total
Health/ Pharmaceuticals	3	3	3	6	9	9	9	7	2	4	55

*Source: Annual Report of Competition Commission of India 2018-19

Combination notices reviewed by the commission as on 31st March 2019

figure 3

Sector	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19	Total
Pharmaceuticals and Health Care	3	4	7	15	11	14	2	9	65

There can be two types of possible anti-competitive agreements: horizontal (intermediate businesses producing the same or identical goods) and vertical (between firms at different

stages in the supply chain). Such deals are illegal under section 3 of the Competition Act of India if they have appreciable adverse effect on competition (AAEC). Like other countries' antitrust rules, the Act of India lays out so-called horizontal "hard core" agreements (cartels). Cartels are basically agreements between rival competitors with a view to cost fixation, quantity limits, rigging offers or business allocations. Such arrangements are believed to be an AAEC, but these presumptions can be refused with regard to some possible advantages mentioned in Section 19 (3)[14].

It is a common axiom prevalent in the society that chemist and doctors usually collude to make profit at the local level. The Pharma companies also approach the hospitals and doctor to promote the particular drug (prescription drug) through their employees i:e Marketing Representatives (MR). It is called the direct marketing also. In 2015 U.S pharmaceuticals companies had spent 20.4 billion U.S dollars to promote the drug through direct marketing. It is to be noted that the direct marketing often leave a field open for collusive activities.

Dominance is natural to the market. Usually the business enterprises long working in the market create a space for themselves. Dominance is customarily characterized as part of the market affairs. There are number of factors in common parlance which decides the dominance of an enterprise in a concerned market. A market size, the share and finance capital of the enterprise, number of competitors in the market, financial capability and bandwidth of undertaking, the customer's reliance on the undertaking, degree of section and exit blockades in the market, purchasing power, market size, dominant position's source etc. There can be no abuse without domination; hence a company's dominance in a relevant market must be established as a first step. Section 4 of the Competition Act 2002 prohibits the abuse of dominant position.

Section 4(2) of the Act prescribes that there shall be an abuse of a dominant position if an enterprise or a group:

[14] Section 19 Competition Act 2002: Inquiry into certain agreements and dominant position of enterprise……
(3) The Commission shall, while determining whether an agreement has an appreciable adverse effect on competition under section 3, have due regard to all or any of the following factors, namely:—
(a) creation of barriers to new entrants in the market;
(b) driving existing competitors out of the market;
(c) foreclosure of competition by hindering entry into the market;
(d) accrual of benefits to consumers;
(e) improvements in production or distribution of goods or provision
of services;
(f) Promotion of technical, scientific and economic development by means of production or distribution of goods or provision of services.

- Impose unfair or discriminatory terms and conditions or prices while purchasing or selling goods or services either directly or indirectly;
- curbs or limits production of goods/ services in the market;
- Limits or restricts scientific and technical development related to goods / services to the bias of consumers;
- Indulgence in practices causing a denial of market access;
- To make for the conclusion of contracts, subject to approval by parties of supplementary obligations, which by their nature or commercial usage have no connection with the subject of such contracts.
- Employs its dominance in one market to enter into or protects its position in other relevant markets.

Section 4 (1) of the Indian Competition Act states, "No Enterprise shall abuse its dominant position". There are nonetheless certain differences in these fundamental provisions. While the Indian law forbids abuse of overriding position by enterprises in general, inessential to say, dominance has been generally defined in terms of market share of the enterprise concerned. There are other factors that come to play role in deciding the influence of an enterprise. Besides market share, the magnitude and resources of the enterprise, size and significance of competitors, economic worth of the enterprise, vertical integration, and need of consumers on the enterprise, extent of entry and exit barriers, countervailing purchasing power, market structure, source of overriding position and so on are various such factors. The Commission can also take into account any other factor which it may regard relevant for the determination of dominance.

There are basically three stages in deciding whether an enterprise has abused its dominant position or not.

- Defining the relevant market is the first stage.
- The second stage is determining if the concerned enterprise is in a dominant position or has a substantial degree of market Power or has monopoly power in that relevant market.

- Determination if the enterprise is in a dominant position or having considerable market power or monopoly power has engaged in conducts forbidden by the statute or amounting to misuse of dominant position or attempt to monopolize under the applicable law is the third stage.[15]

Section 4 defines dominance as "a position of strength, enjoyed by an enterprise, in the relevant market, in India, which enables it to— (i) operate independently of competitive forces prevailing in the relevant market; or (ii) affect its competitors or consumers or the relevant market in its favour". It is valid to note that the act does not differentiate between passive or active market powers. The Act evidently states that there shall be a misuse of dominant position if an enterprise directly or indirectly, imposes unfair condition in purchase or sale of goods or services.

Reconsidering the practice of doctors of limiting competition by prescribing particular costlier drugs when cheaper ones are available. Even if it is legally impertinent to address it as an anticompetitive agreement under section 3(4), isn't it plausible to treat it as an abuse of dominance under Section 4(1)(c). As CCI has held in many cases, if a party enters into an agreement that restricts its choice, it shall not be regarded as a breach of Section 4 until there is adequate ex ante choice of suppliers (in this case doctors).

This malpractice of doctors prescribing particular brands for even non-medical reasons is basically a matter of professional ethics rather than competition laws, hence, It is highly unlikely that the Medical Council of India would treat this as professional misconduct to deregister the practitioner under section 24 of the Medical Council Act, 1956. It calls for a code of ethics and enforcement by the Medical Council of India, pharmaceutical industry and IMA. A fair and transparent relationship between producers and medical professionals can definitely help.

In order to break the dominant position, the EFD (Essential Facilities Doctrine) is commonly used. This has brought many people involved in competition and competition policies a great deal of focus. This is also known as Third Party Access or Open Access in common jargon. The doctrine requires a monopolist/dominant corporation to offer a facility that it owns and is important for successful competition (which is impossible to replicate). Indeed, such duty runs contrary to a company's traditional right to pursue unregulated commercial operations.

[15]Competition Law and the Pharmaceutical Industry, Centre for Trade and Development, New Delhi (2010)

Therefore it is very important for the doctrine to have substance to be circumscribed enough. The doctrine comes from the American anti-trust legislation for about 100 years now.[16] A significant constraint of the functioning of competition is the limit to joining new businesses on the relevant market. If a company that has supremacy of the market in question owns an asset or facility required for market access and it is not readily reproducible at reasonable cost for the short term nor can be interchanged with other products/services, and the company does deny sharing it with its rivals at a reasonable cost without sound reasoning, is called EDF.[17] In order to apply this doctrine, the doctrine has to qualify the following conditions:

1. A dominant firm is in control of the facility in the relevant market.
2. Competing firm lacks the ability to reproduce the facility in real terms.
3. The real need of access of that facility in order to compete in the relevant market
4. And it is possible to provide the access.

On a plain reading if the Act, one cannot find the EDF mentioned anywhere in the Act. However, the competition Act 2002 has the sufficient text and structure to enforce this principle. Section 4 which prohibit the abuse of dominant position says under section 4(c) that the refusal of market access to others by a dominant party would be an abuse of dominant position. It is also the Commission's responsibility to eliminate activities with adverse effects on competition in compliance with Sections 18 and 19. Specifically, the deciding factor limiting the growth of competition is covered in sections 19(3) and 19(4). It also defines the formation of hurdles for potential entrants, elimination from the market of existing rivals, etc. and requirements for assessing dominancy by business market share, scale and strategic value, etc.

The regulatory laws regarding the pharmaceutical sector aim to promote good quality of drugs but at affordable prices and at the same time aims to promote the innovation in this sector. The recent Covid-19 shown the entire world the importance of availability and affordability is a great concern but before that developing the drug is utmost important. Robust public procurement system and single click information about the drugs on the public platforms can be one of the easy solutions to tackle problem of affordability. In this highly market centric

[16] The essential facility doctrine is an exception to the duty imposed by section 2 of the Sherman Act on enterprises.
[17] Jaivir Singh, *Is there a case for essential facility doctrine in India?* CRIC working paper 04, CUTS institute for Regulations and Competition New Delhi (September 2013)

time, a sound competition policy in tandem with the other regulatory laws is much required so that sectors like pharmaceuticals can be made more dynamic to meet the need of people.