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Competition Law and Pharmaceuticals

Saubhagya[a]

[a]Nirma University, Ahmedabad, India

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Due to the recent pandemic and the ongoing advancements in pharmaceuticals, governments today recognize the crucial socioeconomic role that this area plays and are keeping a careful check on it. India is also not alien to it. In order to structure the industry, it has been carefully evaluated. It has been developed to achieve the same goals with far better regulatory organizations and legislation. During the epidemic, the Indian pharmaceutical business was unfortunately treated as an unorganized sector, with several scams and swindles that benefited from public ignorance and desperation being regularly exposed. The following discussion shall discuss the steps taken by the authorities in regards to the competition laws to solve the given problem.

Keywords: *competition, law, pharmaceutical.*

INTRODUCTION

With India playing the leading global role as a major hub of pharmaceuticals, constant quality controls have become the need of the hour with an aim to build the market at a premium standard on the global stage. The right amount of balance to strike between high-level qualities of product & maintain a sizable profit gap and welfare & accessibility is the main area which the pharma companies find hard to handle. While health plans are thought to be important to assure fair access to healthcare services, the industry views them as hostile to

R&D. As a result, competition law must work in tandem with the pharmaceutical industry's different laws, rules, and regulations.

The absence of adequate monitoring of the practices that take place in the sector and non-accountability of the breach of compliance gave Competition Law an important role to carry on the regulations involved in these practices. With the increase of malpractices and power position misuse that has come up in a recent abundance of demand, competition law in pharmaceuticals is an important sector to research into. The given article would follow the same line and discuss the authorities and concerned actions taking place under the umbrella of competition regulation.

COMPETITION LAW AND ITS CONCERNS

Quality and safety standards for goods and services assist consumers by ensuring a minimum level of quality. Businesses or groups of enterprises in dominating positions, on the other hand, may use rules and standards to prevent new businesses from joining the market. Such activities are brought to the notice of the appropriate section on power abuse and exclusionary practices by such activities. The majority of pharmaceutical businesses polled admitted to a collusive activity in the industry. Among the fraudulent acts were doctors writing irrational drug prescriptions in exchange for kickbacks from pharmaceutical companies. Drug manufacturers, wholesalers, retailers, and Medical Representatives all collude in the distribution chain. This has prompted severe worries regarding the supply of vital pharmaceuticals at an affordable price. It also endangers competition by delaying generic entry and raising the risk of monopolistic conduct in the industry.

In recent years, mergers and acquisitions have become increasingly common. The top ten transactions in the first half of 2014 totaled $90 billion. Historically, pharmaceutical transnational businesses with headquarters in industrialised countries have relied on research and development to provide a steady stream of new chemical entities. Several alterations, however, have occurred. To begin with, many companies are dealing with patents that are about to expire, which can account for up to 70% of total sales in some cases. The second factor

is the increasing rivalry in the environment of countries like China, India, and Brazil. These shifts have resulted in the death of the research and development investment paradigm, as well as a wave of mergers and acquisitions with huge research and development-based global firms purchasing generic companies with prospective new medication pipelines.

PROBLEMS IN PHARMACEUTICAL COMPANIES

In recent times we have seen a large portion of the main players in the sector selling limited or entire businesses resulting in partial or complete acquisition. In companies who are selling completely, we see a shift of their company to energy or finance services and the ones who did it partially are meeting ends to stay and grow in the same sector. The ongoing exits by top players have resulted in hollowing the pharma industry in recent years. The issue driving these sudden quits has to be the incoming international competition in front of which their staple production of their own. Pre-2005 they created a stagnant protected market for themselves that would allow generic products to sustain accompanied by the low investment and availability of research and development in their niche.

The contributing fact also remains that the structuring by the Indian companies of the marketing chain has a resemblance to foreign market chains because of the adoption and inspiration from the same. The evaluation at which the majority of these pharmaceutical companies stand makes them tempting enough to many players, whether they be in or outside the sector, for ownership. The complexity that these companies face majority comes from their selling of drugs which are limited to generic drugs. They lack the infrastructure and resources from all fields of excellence hindering their way to making progress or making new and better drugs at a large scale across the country. With all said, there is a possibility of low-cost drugs which are generic in fact may start experiencing higher prices not only in India but also at a global level due to the large number of Indian companies continuously exiting the market. In the case of many other companies who have not exactly quit the pharmaceutical sector entirely, they still choose to shift their focus towards other products and form them as their core. Example of the same JB chemicals in Russia which diverted its main market evaluation to Johnson & Johnson which earlier stood upon 'Doktor mom'.

Information asymmetry that exists in the sector is a huge failure in the Indian pharma market which keeps the customers at an advantage almost always. The abundance of options available doesn't provide the solution the same as the ability to choose is indirectly limited by the limited or even misinformation that they have. The said problem needs to be out attention upon soon.

Regulations put by governments- Government policies in India has known for their regulatory nature in India for not providing a keen market for companies. The pharmaceutical sector is not alien to the same. Under the regulatory framework of Indian Law, the end prices of drugs that constitute 'bulk drugs' is regulated by DPCO 2013 (Drug Price Control Order). This resulted in a rapid surge of drugs that constitutes the bulk drugs increasing from 74 to 348. This seems to have economic tension within the pharma sectors leading to the existence.

USFDA checks - In recent times we saw the company Ranbaxy which had to pay for non-compliance occurred in their generic drugs and it took a toll on the company of a price as high as $500 million. This resulted in a domino effect in which the USFDA (United States' Food & Drug Administration) amped up its frequency of surprise checks and as a by-product of the same spark, USFDA started a new office in India located in Hyderabad. The same was opened to keep in check the Indian pharmaceutical products, in particular to all the drugs which get imported by US from India, running through quality checks and expected standards. Though the common notion still prevails of India and its pharmaceutical market being the producers of below standards and generic products, however this shall not result in higher scrutiny and harsh checks which Indian companies has to deal as compared other global companies.

COMPETITION COMMISSION OF INDIA AND PHARMACEUTICALS

The Competition Commission of India (CCI) has recommended the creation of a National Digital Drugs Databank and strict enforcement of drug quality standards to boost price competition. We examine the findings and recommendations of the CCI's market study in the pharmaceutical sector in India. Generic drugs account for about 43.2 percent of out-of-pocket healthcare expenditure in India, according to the Council for Cost Control and Information

(CCI). When comes to raw materials, the pharmaceutical industry is heavily dependent on China for these materials which are popularly known as Active Pharmaceutical Ingredients (API)[1]. These APIs also known as bulk drugs as described earlier, are majority imported from China (around 70%) to meet the requirements. Another challenge comes from the development of a niche of fake dupes of high-valued drugs due to both the absence and cost-effectiveness of the drugs of high quality available. This not only creates a negative impact on the business but also is hazardous for the public at large. For the promotion of three drug parks in India, pharmaceutical came up with a scheme recently in hopes of growth. Under the scheme, adjacent to land equipped with compatible infrastructure facilities there would be the establishment of a bulk drug park which will have exclusive functions such as manufacturing of APIs, DIs, or KSMs, common waste management system. The goal of the scheme is to cut down manufacturing costs of bulk drugs, increasing competition in the domestic drug industry.[2]

ABOUT THE COMPETITION COMMISSION OF INDIA

After the recommendation of the Raghavan Committee, the Competition Act, 2002 replaced the Monopolies and Restrictive Trade Practices Act, 1969 (MRTP Act) Under the same Act, the Competition Commission of India (CCI) was established. The administration, implementation, and enforcement of the act occurred in March 2009. The members and chairman of the commission are duly appointed by the central government.

FUNCTIONS

1. Elimination of wrongful practices causing adverse effects on healthy competition in the market. Promotion and sustaining of healthy competition at the same time, insurance of

[1] 'Active Pharmaceutical Ingredients: How dependent is India on China' (*The Economic Times*, 29 June 2020) <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/active-pharmaceutical-ingredients-how-dependent-is-india-on-china/videoshow/76694203.cms> accessed 26 June 2022

[2] Gagandeep Singh Dhillon, 'Explained: What is a bulk drug park, and why does Himachal want one?' (*The Indian Express*, 2 November 2020) <https://indianexpress.com/article/explained/what-is-a-bulk-drug-park-and-why-himachal-wants-one-6911710/> accessed 26 June 2022

free trade in the markets. And utmost priority to protect the interests of the public wellbeing and bring to them the best offerings.

2. Opinion making and recommendations will also be a key role of the commission. Authorities established under law shall refer to the commission and assume them to conduct influencing expertise on the pharmaceutical market competition concerns.

RECOMMENDATION OF CCI

The report by CCI[3] emphasized upon generic pricing resulting in effective competition and more accessibility due to affordable healthcare. Following, the state shall also promote more firm quality regulations accompanied by a variety of regulating and testing capacities to be used to achieve more diverse standards of quality. A recommendation to set up a mechanism that would help in generating awareness regarding quality concerns, and the capacity to build and harmonise training was recommended by CDSCO (Central Drugs Standard Control Organisation). The same was suggested to be implemented across the country which would help in achieving better quality standards in the country. More recommendation included the formation of Digital Drugs Databanks which was made available to all the players included in the sectors from regulators to consumers to resist the problem of information asymmetry. The CCI also advised that the frequency of drug testing be increased, as well as the capacity of drug testing labs.

Other than the recommendation given by the CCI there are various ways by which the sectors can be improved. These suggestions include -

In the sector, any agreement between any players regarding any field is its manufacturing, distribution or acquisition, etc, which may directly or indirectly have an impact on competition (AAEC) in a negative way within the boundaries of the country shall amount to an offence under Competition Act 2002[4]. Within the markets prices that are fixed, limited, or

[3] Gorky Bakshi, 'CCI report on 'Market Study on E-commerce in India' (*Jagran Josh,* 8 January 2020) <https://www.jagranjosh.com/current-affairs/cci-report-on-market-study-on-ecommerce-in-india-1578485861-1#:~:text=The%20Competition%20Commission%20of%20India%20%28CCI%29%20has%20released,to%20understand%20the%20performance%20of%20e-commerce%20in%20India> accessed 24 June 2022

[4] Competition Act, 2002

regulated by the parties of horizontal agreement are constituted under *Anti- Competitive agreements.* Coming in terms with vertical restraining agreements which often involve tie-ins, refusal to deal, exclusive supply and distribution agreements are permissible to the extent that it is under the scope of AAEC.

The most important hand in the body of the pharmaceutical sector is policy's efficiencies to execute. A positive sign in the same direction comes with the autonomous watchdog CCI, being allowed to perform its function of supervising all the acquisitions and alliance that takes place in the pharmaceutical market. The effective functioning has to be credited to the amendment of the Competition Act of 2002 which order the government to increase the power and scope of the said commission and strengthen itself as an autonomous body. In order to assist the CCI the option of establishing a Standing Advisory Committee of pharma specialists is directed. The committee may play its role in the shortcoming of CCI, whenever the medicine prices are not in the control of the commission the committee may come in and form a nationwide pharmaceutical scheme that would be legitimized enough that the same would be enforced by the government itself. As the prices of the critical pharmaceutical would come in control across India, multilevel policymaking may be further implemented in order to curb the ongoing increase in partial or complete acquisitions of domestic companies creating a more favourable and healthier growing environment. This may amp up the operating and increase the values of the companies in values as opposed to rapid acquisitions and mouth-watering evolution given to MNCs and the generic market of India shall develop and grow

SSNIP test essential refers to a test that is used to analyse the fluctuations in the price of the product in the context to what extent it has increased, the shift of consumer behavior due to the fluctuation, etc. Indirectly the SSNIP test is used to test the market power held by the product. When there are many treatments available, like in the case of medications for stomach pain or headaches, a slight price increase for one kind of headache medication might enable the customer to move to the other type of alternative. This ongoing battle persists in several economic sectors or industries. The second type occurs, for example, when a disease, like TB, only has one therapy that is believed to be successful in curing TB, and even if the price goes

up, customers would still choose the same product since there isn't any other medication that can treat TB. The scenario is the same for many illnesses. As a result, a single drug frequently has a substantial market share. Because demand is rigid, illegal arrangements are created to manipulate the market. The latter type of competition is what makes it more challenging to regulate the pharmaceutical sector.

CONCLUSION

To assess the importance of standard creation and regular interventions of the authorities to keep everything in check and the consequences linked to the same is essential to deeply understand and come up with a solution that may affect the companies in the Indian pharmaceutical sector. The most important light should be shed upon the companies not opting to risk the safety standard. The same structurisation and resource development should be there at the national level. Clarity and scientific optimising method should be adopted in order to promote compliance along with creating a sense of responsibility among the companies. This shall result in the growth and improvement of the pharmaceutical sector of India and make it a reliable global leader in the same.