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THE INTERFACE OF PATENT AND COMPETITION LAW IN PHARMACEUTICALSECTOR: AN INDIAN SCENARIO

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ABSTRACT
Patent and competition are interlinked with each other. Where on one hand, patentprovide an exclusive right to inventor for his invention/creation for a particular period of time and motivate him for further R& D and promote science and development to protect the humanity. On the other hand, patent also restrict common public from using such invention to protect human health. In such scenario, the competition will occurred when such inventor try to utilize his monopoly rights and indulge in anticompetitive practice and abuse his dominant position in health crisis like corona pandemic. Therefore, in this article, I have examined the significance of these two law in the Pharma sector and their influence on public health.
Keywords- Patent, Intellectual Property Rights(IPR), Intellectual Property (IP), Competition, R&D , TRIPS (Trade-Related Aspects of Intellectual Property Rights Agreement), WTO (World Trade Organization) , Anticompetitive Practice, Abuse of Dominant Position etc.

INTRODUCTION:
As per the government data the domestic market turnover of Indian Pharmaceutical industry stood at Rs 1.93 trillion lakh crore in the year 2023 and export of bulk drugs. drug formations, ayush and herbal products stood at US Dollar 2.27 billion in 2022 and is expected to increase to US Dollar 2.47 billion in 2023. Thus in terms of volume Indianpharmaceutical industry is third largest in world and stands at 14 position in value. The legal provisions and practices followed in the health sector have a broad influence on the industry for it being a sensitive field, both from the consumer and the business perspective. Being a sensitive sector the investment in R&D to develop new combinations and medicines is huge and the industry is concerned to protect patent on the product developed by itand the development of new goods, which are to a large

degree covered by intellectual property ('IP') laws guaranteeing the protection of intellectual property.

However in the era of Globalization and multilateralism where every nation is trying to protect its knowledge and innovation, the TRIPS, which has been accepted by the member nations of World trade Organisation(WTO) as the minimum standard with respect to the notion of a patentable object and all the nations of the WTO are required to abide the terms of TRIPS there is a threat of large companies having financial resource acquiring disproportionate market share, thus attending a stage where it could dictate price of the medicines as per its whims. This situation will lead to competition law issues.

In order to overcome any such situation where pharmaceutical companies may attend a dominant position and mauver the drug prices in such a manner to maximise its profit by showing scant regard to the rights of the consumer, thus defeating the mainobjective of TRIPS, which is to secure and enforce IPR bycontributing to the advancement of technical growth andfacilitating the sharing of information for the collective benefit of technology creators and users, thereby enhancing social and economic well-being through a careful balance of rights and responsibilities.

The licencing and pricing of the pharmaceutical product is regulated in India in form of Section 3(5) of the Competition Act 2002(Act) as India recognises the need to protect the pharmaceutical industry for investment in R&D but the rights of the pharmaceutical companies has to be harmonized with the social obligation of the government which is to ensure that the state ensures the availability of essential medicines at affordable rate.

Global studies have shown that the pharmaceutical companies have tried to artificially regulate the prices of price of drugs through horizontal as well as vertical agreements. These companies have been found to enter into agreement to limit the supply of drugs in the market thereby causing artificial shortage which leads to escalation of price of the drugs. These companies have also been found to enter into agreement with doctors and hospitals thereby affecting/influencing the supply chain thereby selling their products at higher price. In order to check such practices Section 3(3) and 3(4) of the Act applies in India which prohibits any such vertical or horizontal agreements between the companies or between the companies and the hospitals thus ensuring that level playing field is provided to the companies as well as the interest of the consumers is protected.

Indian pharmaceutical industry is a growth story in itself and Government of India in its ‘Pharma Vision 2020’ had discussed about India to become a main centre for drug discovery.In 2020-21 budget the health ministry had been granted sixty five thousand tweleve crore dollar for health insurance under ABPMJAY Scheme. 2019-20 Economic survey had mentioned that Govt. Expenditure had been increased to 1.6 % in health sector and it is also expected that these expense will see robust growth at around 9-12 % in next five year and India will become one of the top 10 country in health expenditure. Through the recent policy launched in September 2023, the government has clearly demonstrated its commitment to positioning India as a major player in the global pharmaceutical market. This commitment is further emphasized by the allocated

capital outlay of Rs 5,000 crore, with a dedicated budget of Rs 4,250 crore specifically for research in priority areas. This significant financial commitment reflects the government's strong determination to foster innovation in the pharmaceutical industry. We eagerly anticipate continued government support and believe that these initiatives will greatly enhance the R&D capabilities of the $50-billion pharma sector, contributing to sustained growth and increased global competitiveness.

Further GoI has brought amendments in the Foreign investment policy in the medical sector and permit hundred percent investment for manufacturing of medical things with respect to certain terms and conditions. Taking note of the rosy picture of the Indian Pharma sector, the global pharma companies are investing through FDI in India in big way. However, the interest of the big global pharma players in India should be both a matter of rejoice as well as matter of concern asit has the potential of distortingthe existing system by expelling/crowding out the smaller players from the market and forming cartel thereby determining the prices of the drugs and setting standard rates for stockists and distributers.The pace of mergers and acquisitions seen in pharma sector in past few years in India is precursor to the things to come in near future.

The growth story of Indian Pharmaceutical sector rests mainly manufacturing and export of generic drugs. India holds the title of being the largest global supplier of generic drugs. Indian pharmaceutical companies cater to approximately 50% of the worldwide requirement for different vaccines, as well as 40% of the demand for generic drugsof USA is met by Indian companies and it supplies around 25% of the demand of medicines in UK is met by Indian companies, thus India has become is an important global player in pharma sector. Indian Pharmaceutical sector is at a crossroad, though it has a huge road ahead for experts who can take this sector new level but there is fight back by global players in order to maintain their position in the international market and these companies are taking recourse to the multilateral agreements like TRIPS wherein theminimum standard with respect to the notion of a patentable object is required to be followed/ implemented by the member nations who are signatory to the WTO agreement.

The primary objective of the TRIPS is to ensure and uphold IPRs, thereby fostering the advancement of technology and facilitating the exchange and dissemination of information. This, in turn, benefits both the creators and users of technological knowledge, while also promoting social and economic well-being by striking a balance between rights and responsibilities..The TRIPS Agreement strikes balance between social objectives of the member nations of WTO with the thin objective of making it possible for individuals to use existing knowledge and encourages innovations. In the pharmaceutical industry where knowledge is power, the advantages of patent is that it encourages private players to spend more in Research and Developmentin order to find a cure for the disease. Ingenuity and innovationhave its own advantages as IPRs attract inventors and innovatorare encouraged to innovate because they hope to increase some prospective positive gain from their innovation. However, the TRIPS balance the social obligations of member nations in form of compulsory licence wherein there is the provision, where new technologies, such as innovative medicine, the cost of development of which could be high, yet

because of its social benefits for the citizens of the member nation, can be brought under compulsory license.With such detailed purpose in mind, compulsory licence for essential medicine which are covered under patent been made compulsory by WTO members, hence Indian Pharma sector needs to exploit the opportunity presented to it by TRIPS and need not worry about the designs of the global pharma MNCs, but the regulators needs to harmonize the patent laws with competition law and ensure that level playing field is made available to all the players and no player is allowed to achieve a dominant position in the sector and thankfully we have law in form section 5 and 6 of competition act.

COMPETITION AND PHARMACEUTICAL SECTOR

With the introduction of new Patent Act the Pharma sector in India is at a crossroad, as it has to meet the challenges brought to its fore by the implementation of product patent system as with the introduction of this regime the investment on R&D is bound to increase, however taking into account the guidelines of TRIPS, the Indian Pharma industry is left with no option but to embrace it and march forward. However, the new patent regime is likely to cause several conflict between Patent Act and the competition as there are several issues with respect to patent law which can be regarded as anti-competitive measures. Further the drug price control policy of the government in order to make quality medicines at affordable price to those who cannot afford high medicine price is also an issue of conflict, however it has to be taken kept in mind that the TRIPS balances the social obligations of member nations in form of compulsory licence wherein there is the provision, where new technologies, such as innovative medicine, the cost of development of which could be high, yet because of its social benefits for the citizens of the member nation, can be brought under compulsory license. But it is a cumbersome process and affects the patent rights of the inventor.

COMPETITION ISSUES BEFORE INDIAN PHARMA SECTOR:

Issue of Dominant Position.

In the realm of business, the concept of 'dominant position' signifies the superior standing of an entity, highlighting its strength and influence in a given market or industry.

a. Operate in isolation from the prevailing competitive pressures within the relevant market; or

b. Yield advantageous outcomes for its competitors, consumers, or the relevant market.

The significance of dominance in competition only becomes apparent once the specific market has been defined. The specific market can be determined by the concerned authority, considering either the specific product market, the specific market area , or both. Dominance itself is not inherently problematic, but it becomes concerning when a dominant player begins to impose its own desires without any opposition, leading to adverse impacts on the sector.

Only when the relevant market has been defined does dominance have significance for competition. A market which may be determined by the Commission with reference to the relevant product market or the relevant geographic market or with reference to both markets means the relevant market.Per se, dominance is not regarded as bad, but when emerges a situation when the dominant player starts implementing its whims and has its way because no

one is in a position to stand to the whims of such a player, such a scenario is bad as it impacts the sector adversely.

Patent act by its nature gives exclusive right to the inventor with regard to its production and royalty thereto. The advantages of patent is that it encourages private players to spend more in Research and Development in order to find a cure for the disease. Ingenuity and innovation has its own advantages as IPRs attract inventors and innovator are encouraged to innovate because they hope to increase some prospective positive gain from their innovation, however the patent is granted for a limited number of years and it is expected that the inventor gains substantially on his invention as a result of the patent granted to it, however there has been situation where it has been seen that the patent holder retorts to evergreening of the product or in order to retain royalty payment it buys out the competitors or frustrate competition.

In the Patents Act, 1970, the term 'evergreening' was not defined, but this type of patent consists of acquiring patents on small changes or improvements or marginal addition w.r.t the efficacy of the product or change in the process of production of the product, with the sole aim to increase the life span of patent beyond 20 years . As per section 3(d) of 1970 Act, does not allow the evergreen patent for merely discovery of known substance if does not enhance the efficacy or threptic efficacy.

The Hon'ble Supreme Court while dealing with Novartis AG Versus UOI where the validity of Sec. 3(d) of theAct, dealing with evergreening of patent. was challenged, after weighing the social and economic factors of the said section upheld the provisions with regard to the evergreening of patent in the patent act and held that the section 3(d) is there to avoid evergreening and enable the state to make available the quality medicines to its citizens at affordable rate.

Compulsory License

As per 2005 the amendment made the patent Act 1970, compulsory licence and product patent have great importance in pharmaceutical industry. Compulsory licence (CL) issue by the government without permission of the patent owner in favour of the other private company with the interest of common public.

As part of the agreement's overall effort TRIPS balances the social obligations of member nations in form of Article 31 of the agreement wherein it has been mentioned as, *other usage without the right holder's permission*, here **other use entails** use by government in form of compulsory licence wherein there is the provision, where new technologies, such as innovative medicine, the cost of development of which could be high, yet because of its social benefits for the citizens of the member nation, can be brought under compulsory license

Therefore, compulsory license is necessary, to protect the need of the common health. The legitimate rationale for the concept of a CL is that the patent should not violate the health right of common public and should serve as a purpose for the promotion of public interest in those which are essential for life and contribute in nation's overall growth. Patents are issued at a fair price that is available to a wide portion of the public in order to benefit from the patented product. Rights to the advantages of a compulsory patent license can be given. It can be said that

there may be specific problems with the practice of compulsory licensing, there is a specific provision which states the patent holder third party to which CL has been granted cannot challenge the CL.This is one of the requirements which have been introduced for compulsory licensing to be issued under the Indian Patents Act. Therefore, after a license has been issued, the original patent holder cannot contest the validity of the licensee's patent.

Competition Act

Section 6(1) of the competition Act forbids the vertical and horizontal coming together of companies which may adversely affect the sector in which the companies are coming together. This has been introduced with the with the sole intention to regulate the coming together of companies in order to eliminate competition from the market and crowding out those who can be it competitor.Section 6(1) empowers the Competition Commission of India to investigate, above any threshold amount of any assets or turnover wherein the merger, amalgamation, acquisition and acquisition of control has been resorted to. While it is up to the concerned party that they wish to combine or enter in agreement for a particular common purpose but before that they have to inform the concerned authority about their purpose and activity otherwise the concerned authority can take an strict action against them.

CONCLUSION AND FURTHER SCOPE:

While the pharmaceutical industry has been boomingwith around 50% of global demand for various vaccines met by India, Indian pharma industry has become is an important global player. However India which has a huge road ahead for experts who can take the sector new level, is yet to exploit its potential to the fullest extentand TRIPS wherein the minimum standard with respect to the notion of a patentable object is required to be followed/ implemented by the member nations who are signatory to the WTO agreement, new opportunities lies ahead for Indian scientists and engineers who have the responsibility to become India a top manufacturing hub and become no. 1 country for it in the world. GoI has taken several steps to encourage the pharma sector and it is the responsibility of the pharma industries to rise to the occasion and exploit the opportunities presented to it. The TRIPS agreement is a reality, however it has to be noted that the main purpose of the TRIPS is to secure and enforce IPRs thus contributing to the overall growth of both creator and common public in health sector and balancing their rights and duties towards each other. The TRIPS Agreement strikes balance between social objectives of the member nations of WTO with the thin objective of making it possible for individuals to use existing knowledge and encourages innovations. In the pharmaceutical industry where knowledge is power, the advantages of patent is that it encourages private players to spend more in Research and Development in order to find a cure for the disease. Ingenuity and innovation have its own advantages as IPRs attract inventors and innovator are encouraged to innovate because they hope to increase some prospective positive gain from their innovation. Hence Indian Pharma companies too need to invest in R&D and become competitive globally. However, the recent changes in the FDI rules in India and the interest of the big global pharma players in India should be both a matter of rejoice as well as matter of concern as it has the

potential of distorting the existing system by expelling/crowding out the smaller players from the market and forming cartel thereby determining the prices of the drugs and setting standard rates for stockists and distributers. The pace of mergers and acquisitions seen in pharma sector in past few years in India is precursor to the things to come in near future. But the pharma sector should take note that the regulations are in place in India to take care of any such scenario where existing players might threat of getting crowded out.

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