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SHOULD COMPETITION BE PROMOTED IN CASE OF PHARMACEUTICAL DRUGS?

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ABSTRACT
Should competition be promoted in the case of pharmaceutical drugs?

Pharmaceutical drugs are highly-priced in India mostly because they are imported from developed countries. Even for the indigenous medicines, manufactured in India, the active Pharmaceutical Ingredient (API) is mostly imported from China. This increases the cost of the drug in India. These factors, by definition, makes these medicines out of bounds for millions of Indians who live below the poverty line. It is anti-competitive as in India, a significant portion of the population cannot afford these expensive drugs. Therefore, we go back to the age old question of whether patent and competition law are conflicting. The Indian pharmaceutical industry is one of the fastest growing industries in the world. It is one of the biggest contributors to the world economy. The only unique industry in which the normal processes of competition does not work in a textbook manner is the pharmaceutical sector. On the demand side, as is observed in other industries, individual consumers do not have the right to exercise their freedom to choose between competing products, based on their features and relative prices, except perhaps standard over-the-counter medicines. The pharmaceutical industry is the most regulated in the world. Yet the regulations do not aptly justify the rewards. The incentive theory goes further. The objective of granting IP rights is not only to compensate the inventor but also, by providing a "spectacular prize", to give incentives to other potential inventors to make the necessary efforts to innovate. Where there is a conflict between competition and intellectual property policies, developing countries like India are inclined towards competition rather than exclusiveness. However, as the invention capability of domestic drug makers grows, a new balance will be needed.

Keywords: Pharmaceutical drugs, (API), industry

I. INTRODUCTION:

One of the Significant indicators of any country's development is healthcare. The status of the advancement of healthcare indicates the nature of the development of a country. This is now apparent more than ever in the light of the Corona outbreak.

The history of the Indian pharmaceutical industry can be divided into three distinct phases. The first phase was the one immediately after independence. Global players dominated the Indian pharmaceutical industry. But gradually, Indigenous pharmaceutical companies were established in India. In 1901, Acharya Prafulla Chandra Roy, a renowned scientist, established The Bengal Chemical and Pharmaceutical Works Limited (BCPW) in Kolkata. The Patents and Designs Act (1911) enacted by the British Government, governed the sector and ensured a robust product patent protection regime. Entry into the Indian market was easy as long as one was ready to pay for the cost for the same. The costly global manufacturers, who had the technological capabilities to bring new medicines to the market were the only ones who could enter the market. Indigenous manufacturers were few and far between. 8 of the top 10 pharmaceutical firms were subsidiaries of multinational corporations. Most of the patents originated from foreign countries, a result of the underdevelopment of British India.

In 1947 in India, at the time of independence, the pharmaceutical market was dominated by Multinational Corporations (MNCs). They controlled eighty to ninety percent of the market primarily through imports from other countries. Till 1970, the Indian pharmaceutical industry produced little in terms of drugs. But gradually over time, these companies are working consistently towards the improvement of health. There is currently a race worldwide for the development of vaccines for the people especially for COvid 19. All patented products including medicines, were foreign and thus drug prices in India were very high-in fact, amongst the highest in the world. Therefore, while the cost of drugs was very high, access to such medicines was not guaranteed even if someone was willing to pay the high prices. India depended heavily on the import of pharmaceutical products. Pharmaceutical products are one of the significant components of the health care administration and its incidentals. The increase in the income of individuals inevitably accompanies changes in lifestyle. This, in turn, contributes to the rise in the

expenses of healthcare of an individual. The growth in the diffusion of health insurance is another factor for the increase in spending on therapeutic products. Lack of affordability, coupled with a lack of domestic competition, had led to a sub-optimal equilibrium.

The conflict between the objectives of competition law and intellectual property law makes it necessary to justify granting IP rights. This is is not the first time that IP Law found itself in a defensive position. The "literary property" debate of the 18th century and the "patent controversy" of the 19th century were the result of the collision of copyright and patents with respectively the principles of common law and free trade. They engendered an important debate on the theoretical underpinnings of intellectual property.

The Patent Act was enacted in 1970, and The Competition Act was enacted in 2002. The Competition Act is entirely silent on remedies specific to abuse of IPRs such as parallel imports and compulsory licensing. Whether patents can be regarded as 'essential facilities' which have to be made available to competitors on fair, reasonable and non-discriminatory (FRAND) terms is a question that has to be considered. The third stage is when India became a signatory to the World Trade Organization (WTO) in 1995.

Around two billion people worldwide have either inadequate access or no acess at all to essential medicines and vaccines. In today's age, most healthcare expenditure in India consists of 'out of pocket' spending by patients and their families, and a substantial proportion of this is accounted for by the cost of medicines. Disease and poverty are interdependent as people are often sick because they are poor and cannot afford the treatment. If a family member is struck by a life-threatening disease, family members often have to sell off existing assets in the absence of adequate insurance. This has in fact happened in the household of the author herself. Yet, many of the illnesses affecting people living in poverty can be prevented, alleviated or cured with a relatively small number of essential medicines if they are available at affordable prices. The general healthcare costs and the price and availability of medicines are deeply responsible for the poor quality of life of millions of Indians.

Corporations dealing with prescription drugs raise the prices of needed medicines every year, compromising patients' health and finances. The brand- name pharmaceutical business model relies on maximizing profits by selling at very high prices to the few, rather than affordable prices to the many. Unless there is competition from generic medicines, there is little incentive for these firms to bring prices down.

In 2011, according to the latest available census data, 69% of total health expenditure in India was financed by private sources, of which "out of pocket" (OOP) expenditure by households comprised 86%. Even for families that fall above the poverty line, spending on healthcare is a major cause of falling below it: as evocatively captured by developmental economics and Nobel laureate Abhijit Banerjee people are only "one illness away" from poverty.

A large portion of Indian population lives in the rural areas and a considerable portion of the Indian population are below the poverty line. It is a major challenge for the pharmaceutical companies, the Government, doctors, and other stakeholders in the health care sector to pass the benefits of the outcome of Research and Development (R&D) to the people who require it.

The proportion of OOP expenditure on health and medicines cannot reliably estimated. This is because a lot of people in India, as mentioned above, fall below the poverty line and even the ones who do have an income are largely unorganized and do not file income tax returns. The Indian pharmaceuticals market is estimated to be the third largest in the world in terms of volume, and one of the largest in terms of value created (Economics Division, 2018). This industry is also a key player not just within India but also across the globe; the Indian pharmaceutical companies produce bulk drugs that are exported to several countries, including the Organisation for Economic Co-operation and Development (OECD) nations.

The Indian pharmaceutical market is unique due to several features even against other OECD nations: a changing patent regime (from product patents to only process patents and then back to product patents), unique nature of competition (for example, branded generics as against pure generics) and other reasons.

The Indian pharmaceutical industry is one of the fastest growing industries in the world and it is one of the biggest contributors to the world economy. The major sales of the pharmaceutical products come from the "Triad" (US, EU and Japan) in the world. The size of world pharmaceutical market in 2014 was around USD 1.2 Trillion and is estimated to be USD 1.4 trillion by 2021. The increasing demand for quality health care and the size of the population are some of the other favourable domestic market conditions in India. Two public sector companies, Hindustan Antibiotics Ltd. (HAL) and Indian Drugs and

Pharmaceuticals Ltd. (IDPL), in the early days engaged in significant R&D, and their R&D efforts spilled over to the private sector through various means—often through movement of scientists.

The key growth drivers of Indian Pharmaceutical market are, increasing in per capita income, better health awareness, increase in health insurance penetration, higher government expenditure on the health care, shift in disease profile and adherence to Indian Pharmaceutical Association (IPA) norms. The growth of the domestic formulation market is driven by lifestyle related medicines like cardiovascular, anti-diabetic, gastrointestinal and respiratory drugs.

According to the IMS health report, it is projected that, US contributes about 41 percent of total sales of medicine in the world, followed by EU and Chain which are projected to spend about 13 percent and 11 percent respectively. Brazil, Russia and India put together contribute about 6 percent of global consumption of the medicine. Given that "free trade" is supposed to be about increased competition, and most people had no idea that a "free trade" deal would impose new monopoly rights for drug companies, North American Free Trade Agreement (NAFTA) and many agreements modelled on it that followed provided a way for the industry to expand its power and keep prices high.

Intellectual property rights play a key role in rewarding investments in research and development, and therefore are critical to promoting innovation and the development of new pharmaceutical products. The narrative of property appeared in both periods as playing an "ex post facto role in legitimating" the granting of property rights in ideas. It also served as a useful organising concept for all the different forms of IP rights that have emerged. IPR protection might not be necessary to foster innovation in all industries. However, pharmaceutical companies rely especially heavily on IPR in the form of patents. Pharmaceutical products can be classified as Original brands, Nonoriginal brands, Unbranded products and OTC (over the counter) products.

There is a substantial difference in the affordability of medicines in India across geographies, income classes, etc. A major question that arises in this case is whether or not innovative pricing mechanisms can be used as a means through which this gap can be addressed.

Original brands are medicines with brand names, marketed by the innovator or companies- which have license to market by the innovator and these products are generally prescription bound. Non original brands are marketed by the non- innovator with brand name, many a times these products will not have patent protection and these products are prescription bound or generic. Unbranded pharmaceutical products are active ingredients, also known as just the generics, marketed as the international non-proprietary name (INN). Whereas, OTC products are other medicine with non- prescription bound and larger substance of which are the over-the-counter.

Expenditure on drugs are generally much lower when treatment is obtained from public or charitable providers as compared to private providers. But between 88 to 99% of respondents across locations still reported that they relied on private providers for drugs, and these figures were significantly higher than those reporting that they had accessed private providers for hospitalization or consultations. In other words, patients relied on private providers for drugs even when they used the relatively low-cost providers for the other components of treatment. In most OECD countries, expenditure on pharmaceuticals is growing at a faster rate than health care expenditure overall.

II. THE ECONOMICS OF THE MARKET FOR PHARMACEUTICALS

The only unique industry in which the normal processes of competition does not work in a textbook manner is the pharmaceutical sector. Competition is important because it compels industry to provide higher quality goods and services at lower prices. In the pharmaceutical industry, competition can motivate brand companies to create new and improved medicines and encourage generic companies to offer less expensive alternatives. However, if consumers are unwilling to pay substantially more for newer patented drugs for which there exist older, possibly slightly less effective, generic substitutes, the ability of patent-holders to charge a premium will be limited.

On the demand side, as is observed in other industries, individual consumers do not have the right to exercise their freedom to choose between competing products, based on their features and relative prices, except *perhaps* standard over-the counter medicines. They have to choose medicines diverting their expenditure from other expenses such as food, nutrition and education. This in turn, would impede the future earning capacity of the members of the family especially which would drag the family down to a vicious cycle of poverty. There is a low elasticity of demand in the pharmaceutical industry due to the

must- have nature of many drugs, owing to the lack of alternatives and regulatory requirements on the range of the products that providers must offer and insurers must cover.

If the family has to sell productive assets or go into debt to finance healthcare expenses, this too could have a long- term impact on their welfare and spending. In India, people often resort to debt to finance healthcare. Both, the prices as well as the availability of drugs is therefore important from both the rival perspectives of what constitutes development. Also, lawyers and economists have to accommodate the possibility that consumers may differentiate between domestic and foreign products even when these products contain the same patentable molecule. Thus an additional channel through which the introduction of product patents and the consequent withdrawal of domestic products may adversely affect consumers, that is, through the loss of product variety.

Given all the above factors access to medicines remain one of the greatest challenges to health policies around the world. A number of developing as well as Least Developed Countries (LDCs) Lack the capability to manufacture the drugs. The exact chemical composition of medicines is mandatorily printed on the packaging as required under most domestic laws of each country. However, most consumers are not qualified or educated enough to understand the pharmacological properties of these ingredients. Neither can the manufacturers reverse engineer the pharmaceutical product merely by looking at the components. Often, generic drugs even if they are manufactured are not as *effective.* Thus, "drugs" cannot be classified as "search goods". The consumers cannot assess the medicine before purchase. Medicines are not "experience" goods either. The consumers cannot determine the characteristics even after consumption as their effects may not be effective for a long time. (eg. HIV or Tuberculosis or). Also, certain medicines maybe *preventive* rather than *curative.*

The pharmaceutical industry is the most regulated in the world. The nature of demand for drugs, the composition of drugs brought to the market and the nature of competition in the drug market over time are all shaped by regulation. There are three main objectives to this regulation:

− securing a reward to R&D to assure a continuous flow of innovative new medications;

− ensuring the safety of drugs; and

− controlling the quantity and enhancing the quality of drug expenditures.

There has been an increase in activity in the generic sector in India. The new drug companies are facing immense pressure to develop generic drugs to maintain their hold in the market. The increase in generic activity can be attributed to blockbuster drugs especially the ones which are facing extinction of their patents. Generally, after the expiry of a patent, generic substitutes are able to flood the market to the extent that the pharmaceutical patent holders' revenues are reduced by 20%. The main purpose of the patent system is to reward innovation. However, these rewards are based on the creation of market power, hence, they necessitate some welfare loss.

Patent policy can be broken into two parts:

- firstly a choice of how much to reward each patent; and
- secondly how to structure each given reward.

The "reward" theory is the most traditional justification for establishing a property rights protection for ideas and is relevant to any type of IP. According to this theory, the inventors should be rewarded for the risks and the investment of time and effort they have made in order to develop a useful to society invention. The reward takes the form of a property right protecting the inventors from free riders. In the absence of this exclusive right, free riders would be able to use the invention without making the investment of time, effort, skill or money required to actually invent it. If a firm could not recover the costs of invention because of free riding, then we could expect a suboptimal level of innovation. The assumption is that during the existence of the exclusive right the inventors should be in a position to recover their investments on research and development.

The incentive theory goes further. The objective of granting IP rights is not only to compensate the inventor but also, by providing a "spectacular prize", to give incentives to other potential inventors to make the necessary efforts to innovate. The process of innovation can be compared to a lottery in which the extent of the investments in a new technology "is motivated by the longshot hope of a very large reward". The objective of the exclusive right will be to provide a prospect of a large reward, not a mere recoupment of fixed costs.

Most legal systems adopt the utilitarian view of IP rights and base their assessment both on the reward and the incentives thesis. However, this is just one aspect of regulating innovation. Public authorities should also strike a balance between the need for invention and creation, on the one hand, and the need for diffusion and access, on the other. Getting a patent is often the outcome of a race to innovation.

Keith Maskus explains that "in setting rules governing IPRs, societies must strike a balance between the needs of inventors to control exploitation of their new information and the needs of users, including consumers and potential competitors working on follow on inventions and innovations. Stated another way, the system should find an appropriate balance between creating and disseminating intellectual property [...] In this context, the system should (1) allow market based incentives for creation, (2) try to minimize the costs of innovative activity, and (3) provide for timely disclosure of innovation or creation and reasonable fair use with economic and social goals in mind."

Pharmaceutical companies also contribute to the economy of the country by creating jobs, developing ancillary industries, export earnings, contributing to the Gross Domestic Product (GDP) of a country. Hence, the growth of pharmaceutical sector of a country is important for the growth of the country's economy. The Indian pharmaceutical market is huge and compared to the world market, the contribution is less than its potential. The focus on other than generic market is the need of the time and Indian pharmaceutical companies constantly searching for new avenues in the innovation driven sector. The constant increase in the size of the Indian pharmaceutical market, due to a change in life style and high demand for quality health care, making this sector as a one of the promising contributors of the Indian economy. The regulatory policies need be improved, especially in the area of patent and price control, to boost the growth and create an impression as the destination for new generation pharmaceutical market.

When competition policy acts beyond competition enforcement, it participates more broadly in the formulation of country's economic policies. In the pharmaceutical sector, competition acts proactively to lower entry barriers and promote competition. Through intervention in pre- grant and post- grant procedures relating to intellectual property, competition aims to strike a balance between the rights of inventors and consumers.

Another area in which competition policy can be especially helpful is public procurement, where procedures often involve collusion and corruption. Successful competition policy in this area, along with working together with anti- corruption policies, will avoid the misuse of public funds and facilitate consumers' access to effective and affordable medication. Competition authorities may also help consumer empowerment through consumer education, facilitating consumer access to information and enhancing the capacity to correctly assess information to make optimal decisions. To conclude, competition policy is a crucial tool for building a transparent, anti-corruption, antimonopoly and consumer-friendly environment. Coordination between competition authorities and other government agencies, such as consumer protection authorities and pharmaceutical sector regulators, will benefit consumers in the long term.

Over the last 20 years, the Indian pharmaceutical industry has increased to the point where it is now the world's largest producer of formulations in terms of volume and of the world's producer of bulk drugs. Where there is a conflict between competition and intellectual property policies, developing countries like India are inclined towards competition rather than exclusiveness. However, as the invention capability of domestic drug makers grows, a new balance will be needed.

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