

**PATENT AND COMPETITION INTERFACE:
ISSUES AND CHALLENGES IN INDIA**

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ABSTRACT

After coming into effect of Competition Act, 2002 India became a country with robust competition regime. The Competition Commission of India (CCI) has been established under the Competition Act, 2002 with the aim of preventing practices having adverse effect on competition. It also aims and promoting and sustaining competition in Indian markets, along with promoting interest of the consumers by ensuring freedom of trade. Similar is the objective sought by the patent regime. Initially the patent protection was granted on the basis of reward theory. According to this theory patent protection is granted to reward the inventor for making public his invention which would otherwise be a secret. Gradually this concept of rewarding the inventor evolved, as rewarding is not only the base of granting patent right. In era of globalization the patent protection is aimed at promoting invention. With the aim of promoting inventions various exclusive rights are granted to the inventor for a limited period. In Indian context that period is of twenty years (20yrs). The shift in the ideology behind providing patent protection made it more society oriented and less individual centric. The objective of patent regime and competition policies are similar to each other. Both are aimed at achieving the same goal i.e. to facilitate market growth by promoting invention and curbing anti competitive practices. Competition policies and patent laws are therefore at many stages complementary to each other acting parallel to achieve their goals. But at many instances their market governance contradicts each other. Various activities done by the patent holder e.g. patent pooling, tied selling, indirect cartelling, exclusive supply is anti- competitive in nature. This paper will analyze the interface in details. It will also focus on effect of contradictory patent and competition practices on various sectors in India.

Keywords: Patent, Competition, Pharmaceutical, Interface, Invention, Anti Competitive Practices, Globalization.

1. INTRODUCTION

“Affluent societies are spending vast sums of money understandably on the search of new products and processes to alleviate suffering and to prolong life. In the process, drug manufacturers have become a powerful industry. My idea of a better-ordered world is one in which medical discoveries would be free of patents and there would be no profiteering from life and death”ⁱ

Patent is a grant of proprietary rights by the government to the inventor, to prevent all others from making, using or selling anything in regard to specific invention. The invention in itself must qualify the test of novelty, inventiveness and capacity of being put to industrial application, to become patentable.ⁱⁱ When an invention complies with this threefold test and does not encroaches in the domain of section 3 of the Indian Patent act, 1970ⁱⁱⁱ, patent will be granted by IPO i.e. Indian Patent Office. Indian Patent regime has always been instrumental in facilitating availability of drugs in the market at an affordable price through the generic drug industry. The key factor being that India provided only process patent rather than product patent during the Pre- TRIPS^{iv} regime. India became signatory to the TRIPS agreement, 1994, as mandated by the WTO. The agreement became effective in 1995. TRIPS agreement contains provisions related to minimum level of protection which the member countries have to comply with, in relation to industrial property. TRIPS further provided that member countries should provide patent protection to both product and process.^v India took ten years to evolve under the umbrella of TRIPS. Indian Patent Act,1970 was amended on March 22, 2005 to include product patenting in its ambit and thus catering to India’s obligation to the global market players as well.^{vi} This marks the inception of a never-ending debate of patent and competition interface in India and its effect on various sectors. To understand the interface between patent and competition and its effect on healthcare sector, it is pertinent to understand the objective behind both.

2. INTERFACE BETWEEN PATENT AND COMPETITION

After coming into effect of Competition Act, 2002 India became a country with robust competition regime. The competition commission of India (CCI) was the regulatory body established under the Competition Act, 2002. It was established with the aim of preventing practices which have adverse effect on competition in the market. It is also aimed at promoting and sustaining competition in the market, protecting interest of the consumers and to safeguard freedom of trade and commerce which is a mandate under Indian constitution as well. The broad objectives of the commission can be described as the following -

- I. To prevent practices adversely effecting competition in the market
- II. Promoting and sustaining competition in the market

- III. To give utmost importance to the benefit of the consumers.
- IV. To ensure freedom of trade and commerce.^{vii}

Similar is the objective sought by the patent regime. Initially the patent protection was granted on the basis of reward theory^{viii}. According to this theory the objective of providing patent protection to an invention was to reward the inventor for making public his invention which would otherwise be a secret.^{ix} Gradually this objective of rewarding evolved, as rewarding is not only the base of granting patent right. In era of globalization the objective of patent protection is aimed at promoting invention^x. And to promote inventions various exclusive rights are granted to the inventor for a limited period. In Indian context that period is of twenty years^{xi}. This changed objective of patent protection and made it more society oriented and less individual centric.

The objective of patent regime and competition policies are similar to each other. Both are aimed at achieving the same goal i.e. to facilitate market growth by promoting inventions and curbing anti-competitive practices. Competition policies and patent laws are therefore at many stages complementary to each other acting parallel to achieve their objectives. But at many instances their market governance contradicts each other. Various activities done by the patent holder e.g. patent pooling, tied selling, indirect cartelling, exclusive supply is anti- competitive in nature. A detailed analysis of this interface suggests that both competition act and patent act are governing market, unaware of the effect of their interface on the market.

3. ISSUES RESULTANT OF INCOHERENCE BETWEEN PATENT AND COMPETITION

India is the largest exporter of generic drugs globally. The pharmaceutical industry of India supplies more than 50 percent of the international demand for vaccine, 40 percent of the demand of generic drug in the United States and 25 percent of all the Medicare demand of United Kingdom.^{xii} India's pharmaceutical industry has grown beyond expectation in the last three decades. As a result of this growth, it became world's third largest producer of pharmaceutical products. The industry has shown tremendous growth over the last few years, rising to US \$36.7 Billion in 2017 and projected to grow to US \$55 Billion by 2020, from US \$20 billion in 2015^{xiii}. It is overwhelming to note that the Pharmacy sector is leaving behind most other sectors in constantly achieving high growth. India is among the top five emerging pharmaceutical markets globally. Due to the ability of the Indian pharmacy companies to produce drugs at economical rates, the cost of HIV/AIDS treatment has gone down to \$400 per year from \$12,000 – a spectacular contribution to global healthcare.^{xiv} As the growth momentum of Indian pharmaceutical market has changed, along with changed the central question related to it as well.

A vast majority of Indians do not have access to healthcare or essential drugs because of

increased drug prices with the increase in grant of patent on drugs post trips compliance by India. During PRE-2005 Regime when there was no pharmaceutical patent granted in India, the generic drug market was flourishing, making Indian pharmaceutical sector a key player in the global market. The scenario changed after 2005, as product patent became reality. Now many generic drugs are being patented in India including vaccines making it difficult for the industry to produce life-saving medicines at cheaper rates with the help of local manufacturers. A major roadblock in the generic drug industry was also created by the recent grant of patent to Pfizer over the vaccine Prevanir 13 for curing pneumonia. The patent has been granted to Pfizer till 2026.^{xv} This decision of India is greatly criticized as it has now prevented various drug manufacturers to manufacture the vaccine at a lower cost. This decision has also affected the international market, as various developing and less developed countries depend on India for drugs at an affordable price. According to a report, sick people around the world depend on Indian drug producers to manufacture affordable generic versions of medicines.^{xvi} India granting patent to global market player is posing a threat to the generic drug dealers in India.

As a result of these issues most healthcare expenditure in India are taken care by 'out of pocket' expenses by patients and their families, and a substantial proportion of this is spend on cost of medicines. An economic analysis of the market shows many anti-competitive issues arising in Indian healthcare sector, because of this monopoly granted to various patent holders. Doctors and pharmacists influence consumer's choice, who in turn are influenced by the medical representatives representing giant pharmaceutical firms. The marketing strategies of various giant pharmaceutical companies who hold multiple patents, is to incentivise their patent within the period of their monopoly. This takes shape of 'supplier induced demand' which in turn results into market failure. The profit driven firms are engaging into more and more anti-competitive arrangements like, cartel creations by various stockists, controlled distribution etc.

Healthcare sector of India took a paradigm shift after the inception of product patent in India. Globalization also had a major role to play as through globalization and growing trend of bilateral treaties, developed nations shifted their concentration to Indian healthcare sector. Because of this various global drug manufacturers have on way or the other started getting various drugs patented in India. A recent example of this has been in the case of *Novartis v. Union of India & Others*^{xvii} through which India is making constant efforts to protecting the market from ever greening and thus providing opportunities to domestic players to keep providing masses with pocket friendly availability of healthcare services.

Apart from this one decision there have been various instances which show the abuse of patent right and anti-competitive behaviour by pharmacy companies. The road to achieve mass friendly healthcare services without discrimination is very difficult to walk on. In the backdrop of recent

developments and the legal and statutory provisions this paper intends to study the effect of IPR and Competition policy the healthcare market and its effect on bringing a cohesive socioeconomic development. The researcher intends to discuss the IPR and competition law issues existing in pharmaceutical sector which has direct effect on health, economy and employment prospects of the individuals and the community. The researcher also intends to discuss the unethical practices prevailing pertaining to irrational drug prescriptions by doctors motivated by kickbacks received from pharmaceutical companies^{xviii} For instance, recently Max Super Specialty Hospital, Patparganj and Becton Dickson India Pvt. Ltd,^{xix} were found prima facie guilty by the Competition Commission of India, of involving in selling of disposable syringes from the hospitals in house pharmacy at double the market price. Moreover, there are issues relating to mergers and acquisitions and FDI in the Healthcare and pharmaceutical sector where MNC acquisition threatens the availability of affordable generic medicines.^{xx}

4. INTERNATIONAL PERSPECTIVE

The interface between IPR and competition law domain has not been unnoticed on the global front as well. The Havana Charter of 1948 of the International Trade organization puts an obligation on the member countries to prevent anti competitive practices and cooperate with the organization. ^{xxi} During the 1960s to 1980s there has been considerable debate on transfer of technology, relationships between IPRs and issues related to competition. In the year 1980 the United Nations general assembly adopted a resolution known as ‘Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices’ which contained rules governing restrictive trade practices and their impact on IPR.^{xxii}

Similar provisions are also there under the TRIPS Agreement which provide for safeguards in this regard and guiding principles for the states in adopting a middle ground between IPR and competition law policies. It also provides that there should be consistency between IPR and competition related policies while the states execute their domestic legislations.^{xxiii} the option of compulsory license is also there to prevent abuse of patents if it is adversely affecting the benefit of public at large. A look at the intent behind trips suggests that the interface between IPR and competition is to be dealt in such a way that in the vent of clashes between both, greater good of the society must prevail. The member countries are also given discretion under the TRIPS agreement to specify abusive intellectual properties under their domestic legislations. Thus Trips give enough discretion to the member countries to regulate their intellectual property in coherence with competition law policies. It is at the end of the member states how well they achieve this objective by achieving a middle ground between IPR and competition polices.

5. CONCLUSION

There is no doubt that IPR and competition law policies have complementary roles and they both ultimately aim at achieving welfare of the consumer. The aim of IP is to promote research and more the research more the competition in the market. But there direct application in the market ends into conflicting execution and therefore is the need of some coherence between the policies governing both. This middle ground cannot be ached by separating both from each other's domain as that would lead to more confusion. IPR and competition law policies should be formed in conformity with each other. The ultimate goal of IPR policies should be to lead to more completion and fair competition in the market. In the same way competition law policies need to be toned down in such a way that they ultimately lead to promote research.

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