AN INTERFACE BETWEEN COMPETITION LAW AND INTELLECTUAL PROPERTY LAWS: A STUDY OF INDIAN PHARMACEUTICAL SECTOR*

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ABSTRACT

Life is the very subject matter of all debates in intellectual property law and public health - whether in terms of access to medicines, sovereignty over living and genetic material, privacy and integrity in the individual body. Healthcare is one of the most basic needs and an inviolable right of every human being. Pharmaceutical industry of healthcare sector is one of the largest, leading and fastest growing industries in the world. It, therefore, is a highly regulated industry as it is an important source of health care for billions of people globally. Further, innovation and technical development now a day's has become one of the key drivers of the economic growth and has posed challenges to growing needs when it is glanced through the competition law and policy prospective and therefore, has consequently gained significant attention. The Competition Act, 2002 was enacted to prevent all kind practices, which are having an adverse impact on competition and thereby upholding healthy competition in the Indian market including a microscopic eye on Anti-competitive agreements, Abuse of dominance and various combinations of mergers, alliances etc. are the key areas requires introspection. Regulation in the pharmaceutical industry is influenced by a host of practices which primarily relates to price regulations, insurance and reimbursements, drug procurement , patent laws, innovation polices, bio-technology and safety policies, drug regulation, drug promotion regulation, drug advertising regulation etc. On the other hand, Intellectual Property regime permits the consumer to have option between competing entrepreneurs and the goods and services they provide in terms of both quality and price. Therefore, IP essentially is a tool for pro-competitive practices as it promises the protection of differentiated intangible business assets. This leads us to find out the interactive approach between competition law and intellectual property law. No doubt there is a considerable overlap in the goals of the two systems of law yet there are also potential conflicts owing to the means used by each system to promote those goals of 'incentivizing and rewarding individual innovators and keeping markets open to their competitors'. Therefore, this study aims to analyse the existing interface between monopolies granted through IPRs and restrictions created to prevent abuse of monopolies under Competition Act in pharmaceutical industry.

Key Words: Innovation, Monopoly, Anti-competitive practices, Pharmaceutical industry, Interface

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A wise man will always allow a fool to rob him of ideas without yelling "Thief."

If he is wise he has not been impoverished. Nor has the fool been enriched.
The thief flatters us by stealing. We flatter him by complaining."

— Ben Hecht

1. INTRODUCTION

Life is the very subject matter of all debates in intellectual property law and public health - whether in terms of access to medicines, sovereignty over living and genetic material, privacy and integrity in the individual body[1]. Healthcare is one of the most basic needs and an inviolable right of every human being. The right to health has been recognized in a number of international legal instruments. In India, although the fundamental right to health is not explicit, it is recognized as a derived fundamental right under Article 21 of the Constitution of India, which is the life and blood of any democracy. In *N D Jayal* v. *Union of India*[2] this right was specifically recognized as a part of right to life under the Constitution of India. Right to access to quality and affordable medicines is an important component of right to health. This is possible when all the stakeholders acts in a manner to succeed in achieving the same. However, it has been seen that this right to have access to quality medicines is compromised in the midst of many anti-competitive practices.[3]

Modern economy, which is characterized by innovation and technological development, has posed challenges in implementation of competition law and policy. Innovation has, in the recent times become one of the key drivers of the economic growth of both public and private corporations. In fact, innovation and new technology cuts across various industries of the economy as can be evidenced in the pharmaceutical sector as well.[4] New markets have emerged and revitalized the economy such as the pharmaceutical sector wherein as a result of the introduction of new drugs including branded and generic drugs, the competition between different markets players have increased at different levels.[5] This has also led to rise in the conflict between the innovator or patent holder of the drug and different market players. The interface between intellectual property, one of the key inducements of innovation, and competition law has consequently gained significant attention in the recent times. This is due to the fact that there appears to be a- conflicting approach between intellectual property and -competition law principles.[6]

2. PHARMACEUTICAL SECTOR IN INDIA

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[1] JOHANNA GIBSON, INTELLECTUAL PROPERTY, MEDICINE AND HEALTH: CURRENT DEBATES, 7 (1st ed. Routledge 2009).

[2] N D Jayla v. Union of India, 2004 (9) SCC 362.

[3] "*Competition Law and Indian Pharmaceuticals sector*" by Centre for Trade and Development (Centad), New Delhi *available at* https://www.cci.gov.in/sites/default/files/PharmInd230611_0.pdf.

[4] Robert Pitofsky, *Challenges of the New Economy: Issues at the Intersection of Antitrust And Intellectual Property* 68(3) ANTITRUST L. J. 913-924 (2001).

[5] D.W. Carlton & R. H. Gertner, *Intellectual Property, Antitrust, and Strategic Behavior* 3, INNOVATION POLICY AND ECONOMY (IPE) 30, 29-59 (2003).

[6] *Ibid*

The pharmaceutical industry is a high technology and knowledge-intensive based industry; being one of the largest, leading and fastest growing in the world. It is one of the most dynamic, research-intensive industry influenced by a web of regulations designed to:

a) promote research and innovation in the design and production of drugs;
b) protect consumers from potentially harmful effects of drugs; and
c) to control public and private expenditure on drugs.

Due to above mentioned reasons this industry falls under the priority sector so far as welfare of individual is concerned.[7]. Despite, all odds, the pharmaceutical industry catering the health care is highly regulated.

Further, it is noteworthy that manufacturing of pharma commodities has grown drastically in terms of production during 1980's in the pharma industry. From 1990 onwards, pharmaceutical companies started to develop due to infrastructure creation and export initiation by the Government and 2000 to 2015 Indian pharmaceutical sector played a vital role in global market because of research oriented and market development approach. The Indian pharma industry being dominated by branded drugs has its global market in recent decade. The share of branded and generic market is approximately 86 percent and 14 percent. The top ten Indian pharma companies hold approximately 37 per cent of the global pharma market beside global average of 4-7 per cent during in year 2008-2013 (DOP, 2013)

The Indian pharma industry ranks 3rd in terms of production (10 per cent of global share) and 14th largest by significance share in lowest cost of drugs in India ranging from 5 to 50 percent as compared to other drug producer of the developed world[8]. Therefore, with such a great growth , it is essential to see its growth and impact in terms of competitive law practices.

3. THE COMPETITION ACT, 2002 AND **HEALTH CARE SECTOR**

Indian Competition law is essentially a legal framework to ensure curbing of monopolistic measures in commerce and industry. The idea is to encourage the competitive activity in the markets in a just, fair and transparent manner and to facilitate a moderated form of rivalry between entities involved in research, development, production, and marketing much as a referee to oversees a match, ensuring fair play and bringing out the best both sides.

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[7] Vishnu S. Warrier, *Patent Law and Competition issues in the Indian Pharmaceutical Industry* 3, **JSSJLSR, 1-10 (2015).**

[8] (Report Equity Master, 2015)

Until 2002, India did not have a competition law regime. The earlier regime consisted of the Monopolies and Restrictive Trade Practices Act, 1969. MRTP was later on substituted by the Competition Act in 2002 and amended in 2007.[9] The Act was enacted to prevent all such practices, which are having an adverse effect on competition and thereby upholding healthy competition in the Indian market.[10] The Anti-competitive practices may occur in a number of ways such as anti-competitive agreements, abuse of dominant position and various combinations of mergers, alliances etc to impact the market and consumer need.

3.1 Anti- Competitive Agreements in Health Care Sector

The term anti-competitive agreement is an agreement having appreciable adverse effect on competition. Anticompetitive agreements include both, the horizontal and the vertical agreements[11].Traditional competition in health care involves one or more elements (e.g. price, quality,

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[9] The provisions of the Competition Act have been notified by the Government in a phased manner and the whole Act is expected to come into force in the near future. Services were also included under the new regime.

[10] See Statement of Objects and Reasons, Competition Act, 2002.

[11] Section 3 of the Competition Act 2002- Anti-competitive agreements.—

1. (1)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.
2. (2) Any agreement entered into in contravention of the provisions contained in sub-section (1) shall be void.
   Any agreement entered into between enterprises or associations of enterprises or persons or associations of persons or between any person and enterprise or practice carried on, or decision taken by, any association of enterprises or association of persons, including cartels, engaged in identical or similar trade of goods or provision of services, which—
   (a) directly or indirectly determines purchase or sale prices;
   (b) limits or controls production, supply, markets, technical development, investment or provision of services;
   (c) shares the market or source of production or provision of services by way of allocation of geographical area of market, or type of goods or services, or number of customers in the market or any other similar way;
   (d) directly or indirectly results in bid rigging or collusive bidding, shall be presumed to have an appreciable adverse effect on competition: Provided that nothing contained in this sub-section shall apply to any agreement entered into by way of joint ventures if such agreement increases efficiency in production, supply, distribution, storage, acquisition or control of goods or provision of services.
   Explanation.—For the purposes of this sub-section, "bid rigging" means any agreement, between enterprises or persons referred to in sub-section (3) engaged in identical or similar production or trading of goods or provision of services, which has the effect of eliminating or reducing competition for bids or adversely affecting or manipulating the process for bidding.

(2) Any agreement amongst enterprises or persons at different stages or levels of the production chain in different markets, in respect of production, supply, distribution, storage, sale or price of, or trade in goods or provision of services, including—
   (a) tie-in arrangement;
   (b) exclusive supply agreement;
   (c) exclusive distribution agreement;
   (d) refusal to deal;

convenience, and superior products or services); however, competition can also be based on new technology and innovation. A key role of competition in health care is the potential to provide a mechanism to reduce the cost of medicine in the health care sector. It generally eliminates inefficiencies that would otherwise yield high production costs, which ultimately are transferred to patients via high health service and delivery costs. Access to medicines and healthcare has five important aspects:

- Availability of supply;
- Price;
- Quality;
- Ability to pay; and
- Access to proper and affordable consultations.

All these above aspects are adversely affected by a number of factors, which range from poverty to poor infrastructure, corruption, market malpractices and lack of awareness. Market malpractices in general, and anti-competitive conduct in the pharmaceutical sector and health delivery system in particular, have serious implications for access to healthcare. Further exacerbating the situation are market distortions and skewed competition norms, unique to the pharmaceutical sector, with particular reference to market concentration, barriers to price competition, and lack of freedom in consumer choice (patients are guided by the advice of doctors and pharmacists).

Moreover, the specific anti-competitive practices of the pharmaceutical system and the health delivery system, which are covered by Section 3 of the Act,[12] are collusive agreements including cartels, tied selling, exclusive supply agreements, exclusive distribution agreements, refusal to deal and re-sale

(e) resale price maintenance, shall be an agreement in contravention of sub-section (1) if such agreement causes or is likely to cause an appreciable adverse effect on competition in India. Explanation.—For the purposes of this sub-section,—

(a) "tie-in arrangements" includes any agreement requiring a purchaser of goods, as a condition of such purchase, to purchase some other goods;

(b) "exclusive supply agreement" includes any agreement restricting in any manner the purchaser in the course of his trade from acquiring or otherwise dealing in any goods other than those of the seller or any other person;

(c) (c)"exclusive distribution agreement" includes any agreement to limit, restrict or withhold the output or supply of any goods or allocate any area or market for the disposal or sale of the goods;

(d) "refusal to deal" includes any agreement which restricts, or is likely to restrict, by any method the persons or classes of persons to whom goods are sold or from whom goods are bought;

(e) "resale price maintenance" includes any agreement to sell goods on condition that the prices to be charged on the resale by the purchaser shall be the prices stipulated by the seller unless it is clearly stated that prices lower than those prices may be charged.

[12] *Ibid*

price maintenance etc. Even practices such as kickbacks to doctors and pharmacists also to be seen as anti-competitive, as they result in depriving patients of the best possible medicines and services at the lowest possible prices. The primary effect of such anti-competitive practices on the health care sector is that medicines and services are available at higher cost, making the poor patient to suffer due to unreasonable cost.

It has also been seen as a practice that the Pharma companies often enter into agreements; including joint-venture arrangements at each stage i.e. manufacturing; research and development phase (for example, to pool patented know-how) and/or at marketing and promotion phase (for example, to exploit complementary marketing strengths). Thus, the pharma sector is likely to be most prone to anti-competitive practices.

3.2 Cartelization in Health Care Sector

The Competition Act mandates that cartels would be presumed to be anticompetitive, but also provides for an efficiency defence, namely that nothing in the relevant subsection shall apply to any agreement, if such agreement increases efficiency in production, supply, distribution, storage, acquisition or control of goods or provision of services[13].

Pharma companies often enter into agreements which results in the boycott of manufacturer's products till a favorable margin is arrived at and where the enhanced margins imply higher prices for the consumers. Hence, directly or indirectly, it determines purchase or sale prices; but the question arises, is it a fair price which can be demanded from the consumer. In most cases, the increase in the price proves to be detrimental to the consumer's interest. In such a scenario, companies are in a position to lure the key influential players such as doctors or the chemists to sell their brand in lieu of commission or higher margin, respectively. However, this may also lead to vulnerability of the consumer in the hands of the pharmacists pushing for brands having higher margins.

In view of the foregoing, it is felt necessary that there should be sufficient teeth under competition law, to implement, enforce and penalize such actions and behavior; and ensure that all market players act under the umbrella of free and fair competition and the benefits of the same should be available to the consumer at large. In this regard, it is suggested that the mandatory generic prescription i.e. prescription by the common chemical name of the drug instead of the branded name, can be useful to check the nexus between doctor and the pharma company.

4. Intellectual Property Regime and Healthcare Sector

The pharmaceutical sector is heavily regulated. All aspects of the life-cycle of new drugs are regulated, from patent application, to marketing approval, commercial exploitation, patent expiration and competition with generics drugs. However, coming to patent and its market regulation in terms of the pharma sector, one also needs to see the patent legislations both in india as well as from global prospective. Patent can be termed as a "set of exclusive rights granted by a sovereign state to an inventor or assignee for a limited period of time in exchange for detailed disclosure of an invention".

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[13] Abhimanyu Ghosh and Deep Chaim Kabir, *Balance of Competition and Intellectual Property Laws in the Indian Pharmaceutical Sector*, 12 JIPR 293-302,(2007).

Patents are important for incentivizing research and development that is crucial for the pharma sector. A patent gives its owners the monopoly rights over the invention. It is a protection to incentivize the innovation process. It gives the right holder an exclusive monopoly while hindering others from offering the product in the market. However, if we look from the completion law and Patent law prospective together, it also suggest that many a times, it can be used as a weapon to restrict competition or in other words, this kind of protections can also become a barrier to the entry of the other operators in the market.

Also with the introduction of GATT, and India becoming a signatory to it in 1994 many changes took place both in terms of legislations as well as operation and functioning in the Indian Market. It was now mandatory to comply with GATT as well as the TRIPS Agreement. Not complying with these standards meant that the defaulting party would no longer be a member of the WTO (World Trade Organization). The pharmaceutical sector also had to comply and meet the minimum standards, as per TRIPS. Therefore, TRIPS Agreement (1995) became a cornerstone Agreement in setting common binding standards. It has mandated that both products and process patents in all fields of technology shall be available. Article 40 of TRIPS is regarded as the inter-section of intellectual property standards and competition law.

The essence of Article 40 can be stated to allow protection for patents while ensuring a balance with competition law. It provides that "*Nothing shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market*."

On January 1, 2005, significant changes were made by an amendment to India's patent law that reinstated product patents for the first time since 1972. "The legislation took effect on the deadline set by the WTO's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which mandated patent protection on both products and processes for a period of 20 years."[14]

Therefore, through the Patent Amendment Act, 2005, not only process patent, but product patent was also introduced for pharmaceuticals and the period of patents was increased from seven years to twenty years. The protection of intellectual property rights, especially patents, is fundamental for ensuring a continuing flow of innovative new drugs. Even when compared to the other pharma regimes in the world, change in patenting regime (product patenting to process patenting to product patenting),

[14] Shamim S. Mondal & Viswanath Pingali, *Competition and Intellectual Property Policies in the Indian Pharmaceutical Sector*, 42 (2) VIKALPA 61-79(2017).

unique nature of competition (for example, branded generics), etc. have made the Indian pharmaceutical market unique.

There is evidence that the pharma sector is more reliant on patent protection for innovation than other industrial sectors. The research and development process for new drugs is costly and risky. Relatively few new chemical entities ever receive marketing approval. Of these, only a few are commercially successful. A sizeable proportion of pharmaceutical manufacturers' revenue can come from relatively few products. Thus, the pharmaceutical market in India owes its current growth and success to the Patents Act, 1970 which brought in the concept of patents in the pharmaceutical sector.

5. Interface between the Regulators In Pharmaceutical Sector

Adam Smith, father of economics once said: "People of the same trade seldom meet together, even for merriment and diversion, but the conversation ends in a conspiracy against the public, or in some contrivance to raise prices."[15]

In India, the Competition Commission of India ('CCI') is the authority which has established under the Competition Act, 2002 (Act) 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. It covers within its ambit all categories of' 'markets' in India including the pharma industry as well.

Though, Section 3 of the Competition Act, 2002 prohibits the anti-competitive agreements, it recognizes the importance of Intellectual Property Rights such as patent, copyright, trademarks etc. It states that nothing shall prevent "*the right of any person to restrain any infringement of, or to impose reasonable conditions, as may be necessary for protecting any of his rights*" enjoyed under the statutes relating to respective intellectual property rights. Section 3 of the Competition Act, dealing with anti-competitive agreements, has made an exception for IPRs. It preserves the rights of the IPR holder to prevent infringement and protect these rights, as long as the restrictions imposed by the agreement are reasonable, ensuring that competition policy does not interfere with the reasonable use of IPRs.

However, Section 4 of the Competition Act deals with abuse of dominant position; its wording is similar to Art. 101[16] of the EC Treaty.[17] This section makes it clear that it is the abuse and not the existence of a dominant position, which is, prohibited by law. It explains what is meant by abuse of dominant position and enumerates the practices, which are to be considered abusive. What is noteworthy and relevant to the current discussion, is that no exception has been created for IPRs, if,

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[15] Adam Smith, The Wealth of Nations: An Inquiry into the Nature & Causes of the Wealth of Nations (1776).

[16] The Treaty on Functioning of European Union, 1957. The initial name of the treaty was Treaty of Rome which was renamed as the Treaty on Functioning of the EU by the Lisbon Treaty with effect from 1st December, 2009.

[17] The Indian competition regime is young; this similarity in law to the EC law would allow the Competition Commission of India to draw on the EC competition jurisprudence, which is considered one of the most developed in the world.

there is an abuse of the right by the owner for his advantage. Thus, competition law takes care of competition in the market and promotes the process of competition, but not the competitors.[18]

On the other hand, Intellectual Property permits consumers to opt between competing entrepreneurs and the goods and services they sell. Therefore, IP is essentially pro-competitive as it promises the protection of differentiated intangible business assets. Although, intellectual property protection *per se* is not abusive but ironically, if it dominates over the market it is only doing a legitimate job of its purpose, namely to create incentives for further innovation. However, when companies refrain from licensing their intellectual property to competitors, they undermine the basic tenets of competition law as well as the spirit of intellectual property protection.

More specifically, patents confer a monopoly status on patent owners, there might be abuse of such monopoly status. Such abuse of dominance is one of the major competition concerns, which may well be set our pharmaceutical industry with the introduction of our new patent regime. "Dominance refers to a position of strength which enables an enterprise to operate independently of competitive forces or to affect its competitors or consumers or the market in its favour. Abuse of dominant position includes imposing unfair conditions or price, predatory pricing, limiting production/market or technical development , creating barriers to entry, applying dissimilar conditions to similar transactions, denying market access, and using dominant position in one market to gain advantages in another market."[19]

Thus, after the enactment of Competition Act, the nexus between Intellectual Property and competition law has been a subject of constant debate among experts as Intellectual Property Laws provide a monopoly right for a limited period of time to the right holder. The European Court of Justice in *NDC Health* v. *IMS Health* has also stated that 'competition law and intellectual property have never been easy bedfellows'.[20] Therefore, in light of universal developments, including the obligations under the TRIPS and the resultant amendments to the IP regime in India, the ability of the Competition Commission of India, to deal with market power created by IP became very relevant.

5.1 Instances of Jurisdictional Interface

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[18] K.D. Raju, The Intellectual Property Rights & Competition Law: A Comparative Analysis, 10 (Eastern Law House, 2015).

[19] Available at http://www.cci.gov.in last visited 19.03.2020

[20] NDC Health v. IMS Health [2004] All E.R. (E.C.) 813; see also Ian Eagles, *Copyright and Competition Collide* 64 (3), C. L. J. 564-566 (2005).

Competition law and intellectual property rights (IPRs) have evolved historically as two separate systems of law. There is a considerable overlap in the goals of the two systems of law because both are aimed at promoting innovation and economic growth. Yet there are also potential conflicts owing to the means used by each system to promote those goals. The conflicts and maintainability of the case involving any pharmaceutical patent filed under Competition Act are discussed and challenged in many disputes. In one of the landmark case[21] the maintainability was challenged on the grounds that the Commission would have no jurisdiction to determine those issues which are pending before civil courts. The commission herein reiterated the opinion of Delhi High Court[22] that "the remedies as provided under Section 27 of the Competition Act for abuse of dominant position are materially different from the remedy as available under Section 84 of the Patents Act. It is also apparent that the remedies under the two enactments are not mutually exclusive; in other words grant of one is not destructive of the other. Thus, it may be open for a prospective licensee to approach the Controller of Patents for grant of compulsory license in certain cases. The same is not inconsistent with the CCI passing an appropriate order under Section 27 of the Competition Act."

The court has also made the observations regarding the interface that The Patents Act is a special act *vis-à-vis* the Competition Act. According to the Hon'ble Court there is no irreconcilable repugnancy or conflict between the Competition Act and the Patents Act. And, in absence of any such conflict, CCI ~~can not~~cannot be barred from entertaining the complaints for abuse of dominance in respect of Patent rights.

In the case of *Hoffman-La Roche v Commission* (1979)[23] it was held by the European Courts while determining the question on authorities responsible for enforcement of the dominance rules in relation to Pharmaceuticals products that large market shares may in themselves be evidence of a dominant position, save exceptional circumstances. "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."[24]

The commission has observed it many a times[25] that the manufacturing companies by colluding with other organizations are involved in anti-competitive practices thus creating trouble for the retailers and in such a case associations comes as a survivor for such retailers.

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[21] Biocon Limited and Mylan Pharmaceutical Private Ltd. (Informants) and F. Hoffmann-La Roche AG & Others, CCI, Case No 68 of 2016.

[22] Telefonaktiebolaget LM Ericsson (Publ) vs. Competition Commission of India and Anr., CCI, Case No. 04 of 2015.

[23] Hoffman-La Roche v. Commission (1979), European Court reports 1979 Pg. 46.

[24] Section 4 of the Competition Act 2002.

[25] Re: Belgaum District Chemists and Druggists Association (BCDA) v. Abbott India Ltd. & Ors., 2017 SCC OnLine CCI 20.

The Competition commission in this regard has stated that there is need to balance the protection of rights of the holders of intellectual property with the prevention of abuse of market power. It further explains that this balance may be struck by differentiating between the existence of a right and its exercise. During the exercise of a right, if an abusive practice is in evidence, which is detrimental to competition, it must assail under competition law.[26] Therefore, under Section 3, IPRs have been protected to the extent that they are reasonable. Unreasonable conditions contained in an agreement will not be thus, protected. On the other hand, when an enterprise enjoys a dominant position and is thus covered by Section 4, it enjoys no immunity for its IPRs.[27]

6. SUGGESTIONS AND CONCLUSIONS

"Competition is good for consumers for the simple reason that it compels producers to offer better deals – lower prices, better quality, new products, and more choice."

--Sir John Vickers

The above study depicts that there lie some issues/ concerns pertaining to Pharmaceutical sector in the current IP and patent environment in India, which needed to address. In order to deal with anti-competitive practices in the pharmaceutical industry and the health delivery system, there are multiple legal and policy options such as competition law, patent law and drug price control at present, which may be utilised effectively. It is to be noted that a number of anti-competitive practices pervade the pharmaceutical industry worldwide, including India. An issue of vital importance, however, is that consumers of formulations are very often not the decision-makers. They are, for the most part, guided by instructions from doctors, pharmacists and other market players.

Therefore, after above analysis, it is proposed to have following in relation to the existing interface:

- That the substantive law that governs the interface between completion law and intellectual property is the Competition Act and it does not provide for express mechanisms and thresholds to guide users on when an intellectual property right becomes an intellectual property wrong thus necessitating the interference by competition law. Therefore, policymakers need to look into this aspect and provide any rules or clarification regarding the same.

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[26] *Bio-Med Pvt. Ltd. v. Union of India, CCI Case No. 26 of 2013.*

[27] Advocacy Booklet on Intellectual Property Rights under the Competition Act, 2002, Competition Commission of India, available at http://www.cci.gov.in/images/media/ Advocacy/Awareness/IPR.pdf, (Last visited on February 14, 2011). See also, Advocacy Booklet on Abuse of Dominance, Competition Commission of India available at http://www.competition-commission-india.nic.in/advocacy/Booklet_AbuseOfDominance11032008.pdf (Last visited on March 14, 2020).

- It is to be noted that as per the current regulatory regime, the adjudicatory bodies does not specifically require the inclusion of an intellectual property law expert and the decisions of the body may be faulted for not addressing the intellectual property issues in competition law as comprehensively as should be addressed. In the circumstances, it is suggested that there be established a special tribunal to deal with issues or disputes relating to interaction between competition law and intellectual property law.
- The issue needs to be addressed through specific guidelines wherein the policymakers should at least provide suggestive mode or the manner in which the relationship can be managed.
- The United nation Development Program (UNDP) has also discussed the effect of interface of IP and Competition Law in relation to Pharmaceutical Patents and suggested that there must be perfect balance in the tools of IP and Competition law in relation to policy implementation.

Finally to conclude, the above study is an attempt_to provide a baseline on the interface between competition law and intellectual property law. The efficiency of the institutional frameworks governing the same was not fully exploited in this research. This is an area that might require further deliberation and exploration as to establish the efficiency of the systems under the attendant legislative framework.