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# Patents rights over a drug and regulation by CCI

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**Abstract**
The pharmaceutical sector in any economy fulfils one of the basic element of health, comprising of the Maslow's Hierarchy of needs, which comprises of safety requirements. This psychological analysis reveals that the pharmaceuticals industry directly impacts the lives of the consumers and necessitates governmental regulation. The increasing mergers in the pharmaceutical sector entail industry specific competition issues where the difficulty lies in determining the post-merger impacts on innovation, which is antithetical to consumer welfare and competition. This paper analyses the manner in which the innovation, consumer welfare and effective competitive practices can only be implemented through regulation by the competition commission. In order to effectuate this reasoning the anti-trust merger analysis by the way of economic and legal tests requires a starkly different approach due to the high technology nature of the pharmaceutical industry.
The unrelenting proliferation of patent rights through mergers and acquisitions poses a substantial setback to the market entry and innovation in various sectors of the economy. The panacea to the issue of patent thickets lies in conflict management which can be best suited to efficient exercise of powers by the competition authorities to identify and remedy patent thickets, through a cogent understanding of the methodology adopted in patent pools, cross licensing and compulsory licensing which ostensibly project the violation of the laws laid down by the anti-trust regime. These issues of innovation can be effectively remedied by an inter-disciplinary analysis, which can only be materialized through the competition commission by addressing the specific requirements of the pharmaceutical industry.

**Keywords:** patents rights over, drug, CCI

## Introduction
In the last decade 264 Mergers and Acquisitions (M&A) have taken place, with the pharmaceutical industry leading in such transactions in comparison to other industries [1]. The study on the Pharmaceutical industry in India suggests that "small firms are unable to expand due to limited availability of resources, at the same time larger firms have resources to invest on multiple capacity expansion as well as technological expansion" [2]. The amendment to the Patent Act in 2005 brought the Indian patent regime in conformity with TRIPS agreement through the inclusion of product patents [3]. These legal changes have propelled the pharmaceutical industry from dependence on mere imitation to greater emphasis on research and development.[4] The foreign direct investment to the extent of hundred per cent has also resulted in greater patenting activates in the pharmaceutical industry [5].
The withdrawal of the internal guidelines, which capped the prices of 108 cardiovascular and anti-diabetes drugs by the National Pharmaceutical Pricing Authority [6], does not bode well for the consumer interest. The logic propounded for such a decision was the inconsonance of the guidelines with the Drug Price Control Order of 2013 [7]. In such a scenario the role of the competition commission becomes pertinent in analysing the economic and competitive issues in mergers and acquisition pertaining the pharmaceutical industry. The market reasoning behind increased M&A in the pharmaceutical industry remains the patent expiration and the excess capacity due to pipeline products [8]. The absence of consumer choice in the prescription drug market, the distribution channels that subsist in the pharmaceutical sector can result in anti- competitive practices whereby the efficiency of the drug is decided by the physician rather than the consumer [9]. The market forces of demand and supply created by a rational consumer, driven through correction by the invisible hand of the market are rendered ineffective through the information asymmetry persisting between the consumer and the drug industry. Thus the increased concentration of operations through M&A impacts the consumer welfare, as the elasticity of demand remains inconsequential [10] as a determinant factor for life saving drugs based on prescription.
The logic propounded by Jean Tirole, the French economist who won the Noble Prize for economics, enunciates the sector specific requirements of regulation [11]. The merger and acquisition (M&A) analysis entailing the impact on innovation in the pharmaceutical analysis requires a custom approach which can be implemented through the Competition Commission of India (CCI).

## Innovation Market Analysis: The long run impacts of Mergers and Acquisitions
The Constitution never sanctioned the patenting of gadgets. Patents serve a higher end— the advance of science.
— William Orville Douglas [12]
As Carl Shapiro appropriately states that "the essence of science is the cumulative investigation combined with hypothesis testing" [13]. Thus the requirement for innovation is the raw material of previous research, which when enclosed within the legal bounds of the patent system, hinders innovation. The gale of creative destruction has provided the tremendous spurt in the growth of various sectors of the economy, which is innovation driven rather than being merely associated with efficient production and

distribution. The perceptions of corporations, being that of a 'boring institution run by sober industrial states' [14] has also drastically been altered by iconoclasts such as Bill Gates and Steve Jobs, who have revolutionized and redefined the role of corporations in society. At the heart of the progressive innovation and competition, lies the incentive provided by the patent system. As Joseph Stiglitz states "the breadth and utilization of patent rights can be used not only to stifle competition, but also have adverse effects in the long run on innovation." [15] Thus the patent system within any jurisdictional bound creates the similar repercussions when allowed to progress unhindered through a rights based approach rather than being regulated to advance societal interest instead of self-interest. The issues currently plaguing the modern patent policy debates include patent trolls, the function of injunctions in patent litigation, hold-ups and the existence of patent thickets [16].

A patent translates into a persistent bargain between the inventor and society, for the disclosure of the invention and resultant reward of a temporary monopoly over that invention [17]. The reasoning of dealing with the issue of patent ponders upon the question of justifiability of their use as strategic tools of devouring the raw material of innovation and competition. Historical evidence proposes that countries with patent laws, the majority of the innovations have taken place outside the scope of the patent system [18]. In countries like the United States, secrecy emerged as a mechanism to shield intellectual property rights [19]. Thus the patent system through its incentive of innovation does not always function as an appropriate alternative whilst the question of stronger patent rights, has provided a breakaway from such a tendency. The aftermath of stricter patent rights results in its manipulation for anti-competitive activities, as the competition authorities cannot impede the march of innovation through a web of patents.

In evaluating the anti-competitive effects of mergers and acquisitions, competition emerging in the domain of innovation remains relatively unrelated with product markets [20]. In the pharmaceutical industry the innovation competition is quite observable as the R&D projects need to seek regulatory approval from the concerned authorities [21]. The Innovation Market Analysis has to be undertaken amidst the pertinent impact of M&A on innovation competition [22], without which the entirety of anti-trust aftermath of M&A cannot be prevented in public interest. The question that is espoused is the mergers and acquisitions leading to entry barriers for the generic industry and hampering innovation. The effects of consolidation in the pharmaceutical industry can impact the availability of drugs in India as well as distort the pricing mechanism against the consumer interest. The issue of impact of combinations on the innovation market has now emerged as an essential criterion in determining the anti-competitive effects of such transactions.

The manner in which the classification of mergers which fall under the purview of the CCI, does not apply to the pharmaceutical industry as competition in such industries is not determined solely on market share but on innovation. The competition issues that have emerged in the pharmaceutical industry vary to a great extent from other sectors of the economy, which necessitate a differentiated approach towards merger analysis. The conflicts that may arise between sector regulators, which in some cases are mandated to resolve competition issues and the competition authorities, does pose the question of jurisdictional conflicts and forum shopping [23]. As per Section 21 and 21A of the Competition Act, the process referencing made to the sector regulator does not resolve the harmonization of the regulation mechanism. Thus the criticism that exists with regard to the innovation market analysis does not encompass the entirety of issues that must be addressed in resolving the constraints of innovation competition in the pharmaceutical industry. Therefore the role of the competition commission is pertinent considering the economic and legal evaluation required in assessing the impact of M&A on innovation competition. Thus the impacts of patents that exist in the pharmaceutical industry and their subsequent control with a singular entity can impact competition. The role of the CCI in evaluating patent thickets and impact on future innovation, with effective tools of compulsory licensing and numerous remedial measures, renders justice to the patent protection granted by the State.

**The Raison d'etre of Intellectual Property Rights**

The economist Schumpeter has commented that '*Nothing can be more plain or even more trite common sense than the proposition that innovation… is at the centre of practically all phenomena, difficulties and problems of economic life in capitalist society*.' [24]

IPR laws provide the legal protection necessary for benefits accruing out of the innovation and thus enhance competition in the market. The US and EU competition laws acknowledge the achievement of an economic monopoly by means of investment R&D and IPR's as a legitimate course of conduct [25]. Article 8 of the TRIPS Agreement requires 'Appropriate measures consistent with the Agreement …' [26] to prevent the abuse of IPR's by the holder of such rights. Thus there exists a substantial role of competition law to meet the ends of a justified exercise of IPR's. The TRIPS agreement imposes higher minimum standards upon its members for all forms of IPR's based on the Berne and Paris Conventions [27]. The perspective from the viewpoint of competition law portrays IPR's as a means of monopolistic control of the market. The focus has been in practice to secure an efficient allocation of resources in the short-run [28]. In order to solve the economic inefficiency of the free rider problem, IPR merely facilitates and redresses the concerns of a market economy, whilst bolstering competition. The allocation of resources due to severe competition will be efficient but the capital available for innovation will be limited [29]. Moreover TRIPS requires minimum standards of protection and permits restrictions on the exercise of private rights. The issues of public health, environmental protection and knowledge acquisition all involve substantial externalities and market failures that IPR's may resolve or exacerbate [30]. At the very core, the dichotomy remains with regard to "overextending monopoly rights on the products themselves and impeding competition" [31]. The question in essence put forth poses a rhetorical dilemma that 'encouraged to compete, how can we punish the success that follows?' [32] Therefore, though the academic debate persists on the inherent flaw of IPR's, the concomitant answer lies in responding to the challenges of interface between two separate spheres of law, rather than establishing the inherent evil within each domain.

**The Refusal to grant licenses: The remedy of Compulsory Licensing and Parallel Imports**

In certain scenarios the right owner can enjoy a position significant market power (SMP), as a result of creation or entering into agreements [33]. In such cases, competition law strives for fostering innovation and investment in research and development, through promoting competition. The grant of IPR does not automatically translate into a monopoly [34], but enables it's misuse under the garb of exercising exclusive private rights conferred by law. The lack of competition produces disastrous effects on the societal interest [35]. The Supreme Court has held that 'whenever the copyright holder exercises monopoly, then any transaction with unreasonable terms would amount to refusal.' [36] A developing economy depends on acquiring technology and information from the developed world, [37] which can be hindered through intellectual property rights. Since knowledge is the common heritage of mankind, the developing countries advocate of maintaining a system, which allows compulsory licensing, thereby limiting the scope of protection and rights available to foreign companies and individuals [38]. The refusal to grant licenses can be termed anti-competitive when it deters competition and to the abuse of rights rather than their mere exercise. The licenses, both compulsory and those voluntarily granted, enable access to the intellectual property right. The restraint that competition law tends to impose is based on the malicious exercise of market power by firms, irrespective of whether the power is the result of intellectual property rights. The conflict of interest arises when the private right holder abuses the rights granted to distort competition and impede the collective interests of society. In order to tackle this fallout of human ingenuity to exploit the law, the remedy lies in identifying the crime explicitly in legislation rather than litigation. Thus an approach of prevention and disillusionment of the obscurity, would serve the interests of not only the public but the private interest.

The unilateral competitive conduct can involve many types of activity, which entail refusal to grant license for patent [39[, withholding vital information in standard setting process and charging unreasonable royalty fees for patent licensing. [40] Compulsory licensing can be granted on the basis of refusal to license and anti-competitive exercises of IPRs by patent holders. The discretionary powers of compulsory licensing must be exercised within the ambit of Article 31 of the TRIPS agreement, which require caution and cogent reasoning of the Competition authority. The disenchantment of Article 31 requires specific situations under which the discretionary powers can be exercised. The Indian Patents (Amendment) Act, 2002 and 2005 under Section 107A has recognized parallel importation. The Patent Act 1970 of India under Section 84 provides for compulsory licensing of a patented invention to an interested person on the grounds of public interest, affordability and manufactured to a reasonable extent in India. The licensing methodology of blockading parallel imports raises critical questions of the nature of anti-competitive activities. The principle to be applies in such situations rests on the exhaustion principle enunciated in the international jurisprudence, which needs reciprocity in the Indian scenario. The circumstances under which the power to allow compulsory licensing are employed must be based on definitive criterions rather than abstract principles and doctrines, which can act as secondary sources of affirmation of a principled approach rather than placing primary reliance on the rule of reason. The prerequisites for invoking compulsory licensing and parallel importation as a remedy has to be understood in the light of the competition act, and must necessarily conform to consultation with the CCI.

Errors or systematic biases in the interpretation or application of one policy's rules can harm the other policies effectiveness. The German Supreme Court has concluded that 'a compulsory license cannot be granted for a pharmaceutical if the public interest can be satisfied with other, more or less equivalent alternative preparations.' In determining whether the assignment of a patent can constitute an agreement or arrangement to lessen competition unduly, the Federal Court of Appeal in Canada has held that the Patent Act does not override the Competition Act and that the two acts could be found to 'operate harmoniously'. Therefore the Patent Act in India must exist harmoniously function with the Competition Act rather than creating power spheres of decision making in the regulation and exercise of the IPR holder.

**Engendering the Patent Thicket**

A patent thicket comes into being when numerous patents covering individual elements of a commercial product are separately owned by different entities. The patent thicket eventually emerges out of the ability of the corporation to patent at an aggressive rate, reducing the scope for further innovation and commercialization by new entrants and those developing upon inventions. Patent thickets increase 'transaction costs, accentuates hold-out problems, and precipitates costly litigation, which prevents commercial development of the affected property.' The prominent implication of the patent thicket is the belligerent practice of active patenting in the concerned industry. The active patenting can lead to an increased cost of entry for new entrants, thwarting the prospects of competition and the very theory of the gale of the creative destruction. Thus in a situation of cumulative innovation where a single product is dependent on other inventions, then the innovation would be hampered though it may encourage invention by large corporations. This scenario can be described in circumstances wherein 'a second- generation technology improving upon a preceding innovation, which leads to the infringement of a patent though the product created is patentable.

**The Patent Thickets Impact on Innovation:**

The risks of standard selection which can result in monopolistic tendencies, requires the intellectual property right holders to commit in advance to the RAND or reasonable and non-discriminatory criterion for partaking in the standard setting process. The options available to the competitors in the market who want to tread through the patent thicket, is diluted to either facing litigation or securing permission, which raises the costs of the business activity. The patent protection grants the patentees a right to engage in activities, which result in competitive pricing, adding to the social deadweight loss. The obstacles, which inhibit the commercialization of the product due to the patent thicket, render the patent system redundant and the philosophy of innovation deluded.

**The Patent Thicket Imbroglio: The impact on Innovation and Competition**

Patent thickets formulate a barrier to entry in the market, if the cost of entry into patenting is increased to such an extent the resultant social welfare is less than in the absence of patent thickets. The ability to penetrate the web of patents requires investment, which represents a risk in terms of the cost-benefit analysis that emerges from a market segment under the demarcation of densely packed patents. The entrant cannot recover the initial investment in such circumstances leading to sunk costs. The sunk costs can result in various forms such as the building brand recognition or the investment in research and development. Patent thickets also debilitate the ability of regular users of patented products by increasing the cost of access through the patent thicket. These costs reduce entry and competition, as the entrants need to recover the costs arising out of the externalities of competition. The coinciding patents produce conflicting issues with regard to the costs involved in transaction between the respective parties. Carl Shapiro identifies two types of transaction costs, which can hinder innovation. The primary difficultly relates to the complements debacle and the tertiary issue relates to the holdup problem. The resolution to the former lies in building a structural co-ordination mechanism between the effected parties and the latter through better information and the ability to challenge patents. The effect of transaction cost in the economic scenario propounds a utilitarian approach towards which a rational individual would always adhere to the better alternative, with less transaction costs. In order to secure permission from the related patent holders, the costs involved include information and negotiation costs, which vary depending upon the expertise involved in procuring the necessitated consent.

The information asymmetry that exists in the market is difficult to counter considering the negotiation and information costs involved in implementing the solutions proffered in the resolution of patent thickets in the markets. The inability of the firms to accurately determine the patent and the costs involved in the patent search, with the eventual infringement after production initiation creates hold-up problems. The problem is likely to arise where the firm indulges in the use of complex technology, as in the case of a mobile phone. The patent thicket quagmire creates 'scientific uncertainty of innovative effort'. Thus the entire essence of the problem revolves around foretelling the losses that may arise in the case of patent infringements, whilst entering the patent thicket. The mere psychological barrier that is created can be contended to be an anti-competitive effect on the entire process of innovation. The tragedy of commons leads to the superfluous consumption of resources without anticipating the inherent loss in continuation with such consumption.

**Compulsory Licensing and Patent Pools: The Remedy with the need for Remedy**

The process of compulsory licensing is an apparent as a danger, when the national governments of particular nations may exercise discretion to choose the firms. The eventual outcome of the licensing process creates loss in revenue, which delays the introduction of new drugs. This phenomenon results out of expertise available with certain firms, who would be deterred from further investment within a time bound manner, creating effectual delays due to compulsory licensing. The compulsory licensing process has been criticized on the ground of the alternative where the government could buy the medicines at one price by subsidizing rather than creating economic distortions in the market. Patent pooling can be termed as very recent phenomenon in India and the lack of case law on the subject, poses impeding challenges to the courts as well as the competition commission. Thus the resolution to the patent thicket poses challenges, which clearly lays a prickly path for not only the courts, but the producers and the consumers. Thus the Indian Patent system does have the ability to tackle the issues arising out of patent pools under Section 68, 69 and 140, without proceeding to the anti-trust laws. The flaws lie in the transaction costs which are required in identifying the patent pool and examining the legal validity in cohesion with competition law, as the issue not only pertains to patent pools but the eventual analysis by the competition authorities. The co-ordination between the two systems in India will produce the desired effect of conciliating the competing interests of the individual and society, based on the rule of reason.

**Conclusion**

'The seeds of knowledge may be planted in solitude, but must be cultivated in public.' -
Samuel Johnson

Thus the active interaction between the competition and intellectual property law provides the critical elixir to their ostensible contradicting objectives of collective versus private rights. The truth lies in the manner in which IPR inhibit innovation and distort as well as delude the market and public into perceiving their protection essential to innovation. The harmonization of IPR and competition law can culminate into socially desirable results, when the judiciary as well as the legislature accepts the inherent evil within IPR protection and its scope for abuse.

The intellectual property rights granted to protect yesterday's innovation sometimes allow that innovator to control today's innovation. This accent to and recognition of the flaw provides the challenge rather than averring that innovation is accelerated by IPR. The presence of a strict IPR regime stifles competition, as the combination of exception under the competition act, can render innovation as a mere short-term process rather than a unobstructed market process. The requirement for an effective Competition authority is the central focus for developing countries, where implementation must be in terms of practice and not mere policy preaching. It requires a legal mechanism of synchronization with the regulatory bodies in the country and the competition commission in order to complement their roles analogous to IPR and competition law. The Competition Commission overlaps with the jurisdiction of sector-specific regulators in India. The domain of competition law enforcement mechanism must be delineated, '*in order to reduce transaction costs and efficiently enhance legal certainty and predictability*.' In the Indian scenario the IPR regulation mechanism requires mandatory consultation rather than being a mere optional criterion of application. The French law does provide for mandatory consultation between the competition authority and certain sectorial regulators. The differences in manner and methodology of functioning of regulatory and competition authorities can result in divergent results, further deluding the interaction between the two

mechanisms.

Thus the expertise available under the competition commission must integrate with the decisions of the regulators, which affect the market and it's functioning. There must be 'establishment of a common, cross-sector regulatory appellate tribunal in order to develop a strong, predictable regulatory jurisprudence', which would lend credit to the very purpose of taking decisions on the restraint of IPR through parallel imports and compulsory licensing, without impeding the rights under broad principle of 'reasonableness'. The prerequisite requirement is of more concrete enunciation of principles under the competition act to synchronize the interface between IPR and competition law in the country. The lack of specific provisions to deal with the separate jurisprudence of IPR and Competition law, necessitates a complete overhaul of the mechanism to deal with their interaction in the market. The Competition Act in its present form is inadequately equipped to deal with the emerging issues of IPR and competition law. There is an urgent requirement to provide clarity to the ambiguity pervading the domain of this interaction. The nature of IPR and its predicament in the varying interests of mankind can be aptly summarized in the words Adam Smith who states 'How selfish man may be supposed, there are evidently some principles in his nature, which interest him in the fortune of others'. In order to counter the inherent want of mankind to subdue one another, it can be overcome only within the restraints of competition law by narrowing down the exclusivist tendency of IPR towards an inclusive approach. Although one can arrive at the conclusion that when IPR's are internally balanced due to deployment of anti-competitive measures, but one needs to holistically integrate the process of granting compulsory licenses through an coordinative approach between the CCI and the IPR sector regulators.

The Patent laws in India have superseding powers over the Competition Act in relation to IPR abuses, which does not effectuate such an integrated approach towards tackling the evolving intricacies of IPR violations. The competition bill amendment 2012 remedies the lack of legal protection granted to know-how and trade secrets under Section 3(5) (i) but does not address the concerns of the nature and form of IPR abuses. In a developing country like India, the IPR-Competition law interface requires a coordinative effort, rather than confining oneself to an isolated domain of expertise, which hinders the resolution of complex issues such as patent thickets, parallel imports and compulsory licensing. Therefore the remedy lies in integrating IPR abuses within the domain of competition authorities through legislative efforts at reconciling the lacunae of defining the offence of IPR abuses and approach towards the grant of licenses by the patent authorities. This provides to the right holder, the legal methodology of harnessing the temporary monopoly granted, within the bounds of Competition law.

"Everyone is in favor of progress; it's the change they don't like", this statement aptly applies to the prevailing necessity to reformulate the patent policy, which emerges from the harnessing innovation to cosseting competition. The densely thicket created by the strategic use of patents not only deters competition but results in a complete dead weight loss to society. The solution lies in co-ordination and consultation between the firms trying to create a resolution rather than anti-competitive conflict. Some authors have also provided for algorithms, which provide the balancing of the patent thicket in terms of commensurate royalty payment, which still does not deter aspect of human tendency of greed rather than the required need, resulting in failed cross-licensing regimes. The difficulty in navigating through the patent thicket lies in plethora of problems that arise when one dwells into the question of solving the patent puzzle.

The quintessential imperfection lies in the solutions to the patent thicket, which yield a patent policy debate, as the flaws exist in the remedies proposed. Patent pooling, cross licensing and compulsory licensing do pose a dilemma of implementation as the impact on innovation is dependent on their rational use, which creates issues on a hierarchical basis of the functioning of various institutions which monitor the patent system. The competition laws of the country, which regulate the misuse of the patents, can pose objections to the patent pools that tend to resolve patent thickets, but under such a disguise the patent pools can also undermine the innovation through anti-competitive behavior. There also exist flaws in the application of the competition laws by the Competition Commission of India, as the patent mechanism remains outside the domain of the anti-trust regime due to the separate regulation mechanism provided under the patent laws of India. As "Greed is the sin of capitalism, envy is the vice of socialism", the moral dilemmas of society require an approach consistent with the larger societal interest than the absolute recognition of individual rights. The socialistic methodology of the Indian constitution advocates such an approach, whereby the fine treading between the dichotomies of rights, renders the exercise of rights, more humanistic than being the black letter law.

The greed of the individual and the envy of society are appropriately balanced, when the competition authorities meticulously balance check the particular exercise of patent rights and not the right itself. The critics of the modern patent system abhor the strategic use of patents as a 'sword to hold up competitors and extract license fees'. The moral justifications for the regulation of patent monopolies has provided true justice to the underprivileged in developing countries deprived of access to expensive medication. The access to antiretroviral HIV/AIDS medication has acted to some extent as a means to clear the corporate stronghold of life through medicine, which can be termed as the 'moral justice of the global IP regime'. Thus there is not only an economic but normative necessity for the legal regulation of the exercise of patent rights, advertently or inadvertently through patent thickets. The amelioration of the patent system from the inherent tendency towards monopolist gains lies in the efficacy of the regulation mechanism and the exercise of discretionary powers in the hands of the government.

The manner in which sector regulators cannot cater to the multiplicity of antitrust issues which encompasses divergent aspects of the legal system, then it necessitates a pro-active role of regulation by the competition commission. The niceties of anti-trust issues, which involve innovation analysis, can be only tackled by the CCI, where diversity of analysis is required where it confined in the case of sector regulation. Thus the role of the CCI is quint-essential in determining the broader scope of issues that result out of mergers and acquisitions in the pharmaceutical industry.

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