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INTERFACE OF COMPETITION LAW AND PATENT LAW

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INTRODUCTION

One of the most debated and complicated sphere of modern legal studies is the connection between the patent law and competition law. On the surface, the two systems seem to be ideologically incompatible: competition law is an attempt to eliminate monopolies and to establish freely competitive markets, whereas patent law is an attempt to grant a temporal monopoly to inventors as a reward of innovation and disclosure. However, a deeper investigation reveals that the two regimes have a similar overall goal the propagation of social welfare and future economic productivity. This chapter will discuss the aims and principles of each legal regime, the main provisions, and how they relate to each other in the context of the Indian law and international commitments and how this interface fits within the structural realities of the pharmaceutical industry.

OBJECTIVES AND PRINCIPLES OF COMPETITION LAW

In its contemporary application, competition law is based on the fact that a free and fair competition in the markets is the most effective way of distributing resources, innovation, and consumer welfare. Competition law regime in India, the Competition Act, 2002 (the Act) was adopted to substitute the older and largely ineffective Monopolies and Restrictive Trade Practices Act, 1969 (MRTP Act). The objectives of the Competition Act as stated in its preamble are prevention of practices, which have negative influence on competition, promote and maintain competition in markets, safeguard the interests of consumers and ensure freedom of trade that are conducted by other market players in India.[2]

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[2] Competition Act 2002, Preamble

The very essence of competition law is known as the market power, the power of a firm to make a profit by selling at prices above the competitive level or by providing lower quality than that of the competitors. Competition legislation does not the prohibit acquisition of the market power through a superior product or innovation but restricts the abuse of it. The Indian competition law applicable to the pharmaceutical patent scenario has three main pillars and they are: first, the anti-competitive agreement prohibition of Section 3, second, regulating the abuse of dominance in Section 4, and the third is regulating combinations under the Sections 5 and 6. The mixture of these provisions deals with horizontal and vertical misconduct that can be detrimental to competition and structural alterations brought about by mergers and acquisitions that can significantly reduce competition within a market.[3]

Other principles that are used in the enforcement of the competition law are proportionality, legal certainty, and a focus on evidence-based decision-making. The enforcement of the competition law demands close market demarcation, dominance determination and competitive impact analysis before a decision can be made on the violation as observed by the CCI.[4] These principles gain a particularly intense significance in IP-intensive industries, like in the area of pharmaceuticals, because the threat of chilling legitimate innovation to over-enforcement is just as much a risk as the threat of under-enforcement to permit unsettling anti-competitive harm.

OBJECTIVES AND PRINCIPLES OF PATENT LAW

In contrast, patent law is based on a theory of bargain, where the state provides the inventor with a time-limited monopoly right on an invention as a reward to the inventor for publicly disclosing the invention to the public. This quid pro quo fulfils the private interests of the inventor in recovering investment and obtaining a profit and the public interest in the knowledge progress and spread. According to the Patents Act, 1970 (Patents Act) that regulates the patent regime in India, the term

[3] Payal Chatterjee, Simone Reis and Dr Milind Antani, "Impact of Competition Law on the Pharma Industry" (Nishith Desai Associates, March 2013)
https://www.nishithdesai.com/fileadmin/user_upload/pdfs/Impact_of_Competition_Law_on_Pharma_Industry.pdf

[4] Competition Commission of India, Market Study on the Pharmaceutical Sector in India — Key Findings and Observations (CCI 2021) https://www.cci.gov.in/images/marketstudie/en/market-study-on-the-pharmaceutical-sector-in-india1652267460.pdf

patent refers to the grant of an exclusive right to a patentee to discourage third parties within India to make, use, offer to sell, sell or import the patented invention without permission.[5]

India has a narrowly limited patent protection. Section 3 of the Patents Act enumerates inventions that cannot be patented such as inventions which are but discoveries of natural phenomena, conceptual theories, or especially for the pharmaceutical industry, inventions of a novel form of the known substance that does not bring about any increase in the known efficacy of the same substance under Section 3(d). This was uniquely intended to avoid the sort of evergreening on which the pharmaceutical sector in the high-income countries actively participates in their patent systems.[6] Even the range of patent protection has a time constraint: in accordance with Section 53, the duration of the rights is twenty years non-extendable since the date of filing.

The goals of patent law in the pharmaceutical industry should also be interpreted within the context of the Indian constitution. The Supreme Court has interpreted the right to health as read out of the right to life under Article 21 and turns out that the constitution of the right to life influences the way in which the courts and regulators consider the exercise of pharmaceutical patent rights.[7] The constitutional obligation to provide access to affordable medicines, therefore, serves as an implicit limitation to the exercise of patent exclusivity, which supports the necessity of such tools as compulsory licensing and intervention by the competition law.

RELEVANT PROVISIONS OF THE COMPETITION ACT, 2002

The Competition Act, 2002 has several provisions which are directly applicable in regard to licensing of pharmaceutical patents. Section 3(1) bans any agreement in relation to the creation, provision, distribution, storage, purchase, or control of goods or even services in India that create or are possible to create an AAEC. The specific section 3(4) deals with vertical agreements such as tying, exclusive supply, exclusive distribution and refusal to deal and compares them with the AAEC criterion. The

[5] Patents Act 1970, s 2(1)(m)

[6] Monika Narayan, "Pharmaceutical Patents, Public Health and the Pandemic" Economic and Political Weekly https://www.epw.in/engage/article/pharmaceutical-patents-public-health-and-pandemic; see also Novartis AG v Union of India (2013) 6 SCC 1

[7] Paschim Banga Khet Mazdoor Samity v State of West Bengal (1996) 4 SCC 37; Consumer Education and Research Centre v Union of India (1995) 3 SCC 42

very nature of patent licensing agreements is vertical arrangement and it can be covered under Section 3(4) in case it has a restrictive condition unreasonably closing off the market.[8]

Section 4 of the Act traces abuse of dominant position and is very important in the context of the pharmaceutical patent licensing. A company is considered dominant when it can be said to be strong in its relevant market and is on a position where it can independently work without the influence of the competing forces or affecting them or the market concerned to its advantage. In the situation of the relevant market, dominance can be assumed frequently when a company has a patent on a pharmaceutical product that has no satisfactory substitute in therapy due to the inherent exclusive rights granted by the patent, which cannot be breached during the entire period of the patent.[9] The Act lists the types of abuse that can be practiced by a dominant enterprise as including demanding unfair or discriminatory terms in the purchase or sale of goods, restraining or restricting production or supplying of goods or services to the disadvantage of the consumers and performing activities that lead to the denial of access to markets.

In Competition Act, section 3(5) is an important carve-out of IP rights. According to it, the right to restrain any infringement of, or to take reasonable conditions, as the need arises to safeguard any of his rights arising under particular intellectual property legislation, such as the Patents Act 1970, is not limited by the prohibition against anti-competitive agreement. This exemption has received significant controversy especially with regards to the definition of 'reasonable conditions'.[10] The CCI has always believed that this exemption is not a blanket immunity and the prerequisites that exceed what is reasonably necessary to defend the right of the patent itself or are used as a market foreclosure

[8] Ishita Singh and Anand Vikas Mishra, 'Competition Law and Compulsory Licensing: Interrelation and Way Forward' (2021) 62 Indian Competition Law Review 14 http://iclr.in/wp-content/uploads/2024/03/ICLR-Volume-62-Article-2-pp-14-29.pdf

[9] Competition Act 2002, s 19(4); Yogesh Pai and Nitesh Daryanani, "Patents and Competition Law in India: CCI's Reductionist Approach in Evaluating Competitive Harm" (2017) 5(2) Journal of Antitrust Enforcement https://academic.oup.com/antitrust/article/5/2/299/3788021

[10] Competition Act 2002, s 3(5)(i); Vishnu S Warrier, "Patent Law and Competition Issues in the Indian Pharmaceutical Industry" (2015) 3(1) JSS Journal for Legal Studies and Research https://jsslawcollege.in/wp-content/uploads/2021/08/PATENT-LAW-AND-COMPETITION-ISSUES-IN-THE-INDIAN-PHARMACEUTICAL-INDUSTRY.pdf

mechanism and not as an actual IP protection are not covered by Section 3(5) and are subject to an analysis through the Act.

The Act in Sections 5 and 6 for regulation of combinations also applies to the pharmaceutical industry, especially in cases where mergers and acquisitions include the pooling of patents. When the combination of such causes or is likely to cause an appreciable negative impact on competition in India, the CCI may block them or conditionally approve them. The pharmaceutical industry has experienced several high value combinations that include patent-holding organizations, which has brought issues concerning the aggregation of the market power by consolidating the IP.[11]

RELEVANT PROVISIONS OF THE PATENTS ACT, 1970

In the Patents Act, 1970, which has been substantially revised by the Patents (Amendment) Act, 2005, in response to the requirements of the TRIPS, there are a number of provisions that are directly concerned with the competition issues. Compulsory licensing (under sections 84 to 92A) is the most potent domestic law tool of remedying market failures caused by the practice of patent monopolies. Section 84 allows any individual to seek a compulsory licence three years following granting a patent on the basis that the reasonable needs of the people with reference to the patented invention have not been met, the patented invention is neither made accessible to the people at a fairly affordable price nor the patented invention is not practiced in the Indian territory.[12]

The general principles which are to be observed in settling the terms and conditions of the compulsory licences are listed in section 89 of the Patents Act, and include the principle that the royalty and other remuneration which would otherwise be due to the patentee shall not be unreasonable, taking into consideration the nature of the invention, the amount of money spent by the patentee in making the invention and obtaining a patent and maintaining the patent. Section 92 also gives the Central Government the authority to give directives to compulsory licensing in matters of national emergency or extreme urgency such as public health crises. This was particularly relevant when it came to

[11] Competition Act 2002, ss 5—6; Ashish Bharadwaj, Vishwas H Devaiah and Indranath Gupta, "Multidimensional Approaches Towards New Technology: Insights on Innovation, Patents and Competition (Springer Nature 2018) https://link.springer.com/book/10.1007/978-981-13-1232-8

[12] Patents Act 1970, s 84(1)

negotiating access to COVID-19 vaccines and India did not use this authority but instead settled on the alternative of voluntary licensing alongside manufacturing deals.[13]

The Patents Act section 107A offers the Bolar exemption which allows the utilization of a patented invention with the aim of getting the regulatory approval of a generic medication without such utilization being regarded as infringement. This clause is important in terms of competition since it cuts down on the duration of successful market monopolization by the original pharmaceutical firms after the patent expiry period has elapsed in form and hence, enables the earlier penetration of the generic market and the competition pressures that come with it.[14]

The licensing context is also notable in Section 140 of the Patents Act which makes void certain contractual expressions in patent licences that are intended to surpass the rights of the patent including a condition requiring the licensee to purchase goods of the patentee as a condition to the licence, a condition prohibiting the licensee to contest the validity of the patent, and a condition requiring the licensee to pay royalties beyond the term of the patent. These legislative clauses limiting contractual provisions in patent licences are indications of a statutory awareness of the fact that patent licences are capable of being used in anti-competitive practices, and are a significant law in place below which no valid licence agreement could be concluded.[15]

INTERNATIONAL FRAMEWORK UNDER THE TRIPS AGREEMENT

The domestic patent and competition law regimes in India cannot be discussed in the seclusion of the international system which is the TRIPS, which is part of the Annex 1C of the Agreement establishing

[13] Dr Payal Thaorey and Anushree Mukte, "Compulsory Licensing of Pharmaceutical Patents in India: Issues and Challenges" NLU Nagpur https://www.nlunagpur.ac.in/PDF/Publications/5-Current-Issue/1.%20COMPULSORY%20LICENSING%20OF%20PHARMACEUTICAL%20PATENTS%20IN%20INDIA.pdf

[14] Patents Act 1970, s 107A; Partha Banerjee and Dr Dakshita Sangwan, "Pharmaceutical Patents, Generic Drugs, and Competition Laws in India: Policy Pathways for Equitable Healthcare Access and Development" Journal of Applied Bioanalysis https://journalofappliedbioanalysis.com/pharmaceutical-patents,-generic-drugs,-and-competition-laws-in-india:-policy-pathways-for-equitable-healthcare-access-and-development

[15] Patents Act 1970, s 140

the WTO and of which India has been a bound member since its accession to the WTO in 1995. The TRIPS Agreement establishes no-less-than minimum standards on protection of the IP that WTO Members are required to adopt in domestic law, but also retains some flexibility that Members can exercise to promote public health and other social agendas.[16]

Article 27 of TRIPS defines the generic standard of patentability whereby patent should be granted to any inventions, products or processes in any area of technology without discrimination under the normal provisions of novelty, inventive step and industrial applicability. In the case of India, the most important impact of Article 27 was that it obligated a period of protection over pharmaceutical and agricultural chemical products under the patenting laws, an obligation that was intentionally left out of the original Patents Act, 1970 to allow India to protect its generic pharmaceutical market.[17]

Articles 31 and 31bis of TRIPS provide compulsory licensing, which stipulates the circumstances in which Members can grant compulsory licences without permission of the holder of a right. Among these conditions are that the right holder has to have negotiated with the entity seeking to obtain a compulsory licence on reasonable commercial terms (with an exception of emergencies), the compulsory licence should be limited to the domestic market of the authorising country (except under 31bis that creates an exception of an export mechanism to countries with inadequate manufacturing capabilities), there should be sufficient remuneration payment, and the right holder has the opportunity to have the decision judicially or independently reviewed.[18] The Doha Declaration of 2001 on the TRIPS Agreement and Public Health made it clear that TRIPS may be construed to uphold the right of WTO Members to safeguard the health of the population and, specifically, to encourage the provision of medicines to every citizen, which is a significant source of political legitimacy to the application of the TRIPS flexibilities such as compulsory licensing.

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[16] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) (Marrakesh, 15 April 1994) 1869 UNITS 299, Annex 1C to the Marrakesh Agreement Establishing the World Trade Organization

[17] TRIPS Agreement, art 27; Dr Ram Prakash Chaubey, "Issues of Patent Law in Pharmaceutical Industry: An Analysis of Emerging Jurisprudence regarding Compulsory Licensing" (2025) 7(5) IJFMR https://www.ijfmr.com/research-paper.php?id=56807

[18] TRIPS Agreement, art 31; WTO "Declaration on the TRIPS Agreement and Public Health" (Doha, 14 November 2001) WT/MIN(01)/DEC/2; Siddharth Gupta, "Compulsory Licensing of Patented Drugs in India: Emerging Legal Challenges" IJLMH https://ijlmh.com/wp-content/uploads/Compulsory-Licensing-of-Patented-Drugs-in-India-Emerging-Legal-Challenges-in-IP-Protection-Pharmaceutical-Advertisement-and-Infringement-Remedies.pdf

Article 40 of TRIPS deals particularly with the overlap of the IP and competition law, noting that there are licensing practices or conditions involving IP rights which prevent competition that could negatively affect trade and hinder the transfer of technology. Article 40(2) allows the Members to stipulate in their legislation licensing practices or conditions that in certain circumstances this may amount to an abuse of the IP rights that may have an adverse impact on competition in the market concerned, and that appropriate actions may be taken to prevent or regulate such practices. This is an explicit international legal power over the application of competition law to anti-competitive pharmaceutical patent licensing, but gives a lot of discretion to Members on the specific form and coverage of such regulation.[19]

SYNCHRONIZATION AND CONFLICT BETWEEN THE COMPETITION AND PATENT LAWS

Competition law and patent law have a relationship that can be described as a dynamic tension that needs to be managed with principled approach rather than as a clash of law fundamentals that will need to be solved in favour of one of the regimes at the expense of the other. Regardless of the fact that both regimes eventually fulfil the same systemic objective to encourage innovation and consumer welfare, the means by which they do it differ and even often conflict.[20]

The typical conflict is the situation where the holder of a patent enforces its exclusionary rights to the extent that they are legal under patent law but which may prove detrimental to competition. An example of a paradigmatic instance is the unilateral refusal to license: a patentee is in no general duty to license its patents and the issuance of the exclusionary right is the pro forma of the grant of a patent. However where the subject of the patent protection is essential to join the downstream market and the denial of licensing amounts to the market being closed to the competitors, the competition law

[19] TRIPS Agreement, art 40; Sumita Subarno, "Compulsory Licensing in India and Asia: Bridging the gap between Patent Enforcement and Public Health" IJLSSS https://ijlsss.com/compulsory-licensing-in-india-and-asia-bridging-the-gap-between-patent-enforcement-and-public-health-in-pharmaceutical-trade-of-traditional-medicines/

[20] Ashish Bharadwaj, Vishwas H Devaiah and Indranath Gupta, "Multi-dimensional Approaches Towards New Technology: Insights on Innovation, Patents and Competition" (Springer Nature 2018) Ch 1 https://link.springer.com/book/10.1007/978-981-13-1232-8

can be legitimately interested to do so. The struggle in this case is not purely technical; it touches on the core of the mission of each legal regime.[21]

The Indian courts and CCI have tended to make the two regimes consistent and not to make one as subordinate to the other. The stance of the CCI on the cases like *Ericsson v. Competition Commission of India* has realised that a patent does not necessarily point towards dominance in the concerned market and utilisation of patent rights is not an abuse of dominance. Nevertheless, the Commission has indicated further that where the exercise of patent rights are coupled with a conduct that is out of the legitimate bounds of patent exclusivity, including the charging of exorbitantly high royalty payments, the provision of discriminatory licensing conditions or the use of tying arrangements, such conduct can come under competition law liability.[22] This method constitutes a subtle perception of the association between the two regimes, however, as has been mentioned, the analytical framework by the CCI in such instances has not always been steadfast or rigorous enough. Another aspect of the harmonisation dilemma is due to the fragmentation of IP procedure and competition regulation in India. The Patent Office, the IPAB (now merged to the High Courts after its abolition), and the High Courts, adjudicate on patent disputes; whereas the CCI and the NCLAT are the only two courts capable of adjudicating competition disputes. This institutional distance ensures that the two regulatory regimes have a tendency to work in silos, lacking sufficient cross-fertilisation of analysis and sufficient coordination.[23]

[21] Richard J Gilbert and Carl Shapiro, "An Economic Analysis of Unilateral Refusals to License Intellectual Property" (2003) PMC https://pmc.ncbi.nlm.nih.gov/articles/PMC34132/; Simon Genevaz, "Against Immunity for Unilateral Refusals to deal in Intellectual Property" (Berkeley Law, 2004) https://lawcat.berkeley.edu/record/1119309?v=pdf

[22] Telefonaktiebolaget LM Ericsson v. Competition Commission of India W.P.(C) 464/2014 (Delhi HC, 2016); Shambhavi Shivani, "Patents and Indian Competition Law: The CCI's Simplistic Technique of Assessing Competitive Impact" (2022) Journal of Positive School Psychology https://journalppw.com/index.php/jpsp/article/view/3550

[23] Indian Institute of Corporate Affairs, "Working Paper on Enforcement of Competition Law on Refusal to License of Intellectual Property Rights" https://iica.nic.in/images/Working%20Paper_Refusal%20to%20License%20and%20Intellectual%20Property%20Rights.pdf

CONCLUSION

This chapter has charted the conceptual and legal environment within which the interface between the competition law and the patent law in the Indian pharmaceutical industry is set. The discussion shows that the competition law and the patent law are united by the common goal to achieve social welfare but address this goal in different and even opposing ways, and their cooperation in the context of pharmaceutical activity presents a complex and demanding task at the level of doctrine and organization. The Competition Act, 2002 and Patents Act, 1970 have provisions that, in very broad strokes, offer a framework that is sufficient to deal with competition issues concerning pharmaceutical patent licensing but the application of the two has not been consistent and co-ordination between the CCI, the Patent Office and the courts has been underdeveloped. The TRIPS Agreement establishes international conditions of boundary in making domestic policy decision, and retains a considerable degree of flexibility in which India has availed, but not necessarily exhaustively exercised, to respond to the needs of the populace in their health matters. The following chapters of this dissertation extend on these premises to look at the patent licensing practices in particular that lead to competition issues, how the regulatory and judicial institutions in India have reacted to these issues, and what lessons can be learned based on the comparative experience in the United States and the European Union.