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ANTI-COMPETITIVE BEHAVIOUR IN THE PATENTED PHARMACEUTICAL INDUSTRY: A STUDY OF THE CASES BEFORE THE COMPETITION COMMISSION OF INDIA

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ABSTRACT

In this post-TRIPS era, the impact of intellectual property rights, especially patents on accessibility and affordability of medicines, is globally discussed. While some argue that these rights create barriers to access and affordability, proponents of the utilitarian perspective contend that IP laws incentivize the production and commercialization of new discoveries or creative works, resulting in overall social welfare benefits that outweigh the costs of these restrictive property rights. However, this argument holds true only if the societal benefits exceed the information and knowledge costs associated with granting IPRs. It fails to hold ground when IP holders engage in anti-competitive behaviour, which imposes a greater deadweight loss on society as the costs of exclusive rights outweigh the benefits of such legally restricted monopolies.

Various international conventions, including the International Covenant on Economic, Social and Cultural Rights (ICESCR), place obligations on states and their machineries to take affirmative measures in protecting and fulfilling the right of citizens to have access to safe and affordable medicines. This ensures that individuals can enjoy the highest attainable standard of health without barriers posed by patents. Consequently, it becomes essential for the state to actively prevent pharmaceutical patents from impeding accessibility and affordability of medicines, including by facilitating market entry and exit options. However, obstructions to achieving this public health goal may be created by patents as the exclusivity granted by patents allows pharmaceutical companies to maintain high prices, limiting affordability for individuals and healthcare systems. This can be particularly problematic in low-income countries, where the cost of patented medications can be prohibitive, leading to inadequate healthcare outcomes and a disparity in access to essential treatments. Balancing the need for innovation with ensuring public health is a complex challenge that requires careful consideration of intellectual property policies and strategies to promote affordable access to medicines for all. The recourse for such impediments created by patents does not lie in the

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patent law regime alone. In this context, by exploring the interplay between intellectual property rights, competition, and public health, this paper aims to shed light on common anti-competitive behaviour, including abuse of dominance, that are prevalent in the pharmaceutical industry, and thereby ultimately contributing to the ongoing discourse on striking a balance between fostering innovation and ensuring accessible and affordable medicines for all. It will also pay special attention to cases brought before the Indian Competition Authority, specifically concerning the Indian pharmaceutical industry. By examining these instances, one may gain a deeper understanding of the challenges posed by anti-competitive practices of a patent holder and explore potential solutions to mitigate their negative impact on the accessibility and affordability of medicines. Through comprehensive analysis and evaluation, this study aims to contribute to the ongoing discussions surrounding patents, competition, and their implications for the pharmaceutical sector.

Keywords: Anti-Competitive, Patent, Pharmaceuticals, CCI, TRTIPS.

Introduction

The pharmaceutical sector is distinguished by anomalous economics and a peculiar confluence of competition law, patent law, and regulatory laws. The success of a business will mostly depend on its R&D activities since scientific understanding rather than manufacturing expertise drives competition in the global pharmaceutical sector. As a result, the drug business has unusually high R&D investments relative to overall sales[2]. Anti-competitive practices are a major concern in the global pharmaceutical industry due to the presence of a peculiar market failure possibility in it. Most of the time, customers are not involved in decisions about consumption, which in this case is of drugs and healthcare services. These anti-competitive practices have a direct impact on the accessibility and availability of medicines and therefore ramifications on ensuring the human right of access to medicines for all. The issue of patents becomes the centre of this debate when essential drugs or lifesaving medicines are patent protected. The Patent Act of 1970 protects the rights of a patent holder mainly by giving him/her a right to exclude others. The extent of this exclusion is in some way limited by the application of competition law and other drug regulations along with provisions such as compulsory licensing, statutory and regulatory exception etc. There is a need to examine the extent to which competition law may intervene and remedy anti-competitive practices and abuses by a patent holder.

The Indian Pharmaceutical industry flourished during the Pre- TRIPS interval between 1970

[2] Sanjib Bhattacharya and Chandra Nath Saha, "Intellectual property rights: An overview and implications in pharmaceutical industry," 2 *Journal of Advanced Pharmaceutical Technology & Research* 88 (2011).

and 2005 wherein product patents were not granted for pharmaceutical products in India. This was possible because the absence of the product patent regime enabled Indian generic companies to manufacture and sell cheaper generic versions of patented drugs thereby ensuring competition in the Indian market. There were widespread speculations that the dawn of a new product patent regime in the Indian Pharmaceuticals will directly impede the access and affordability to medicines in India. Many studies estimated that prices for products with foreign patents would increase by between 100 and 400 percent in the absence of any price controls.[3] Upon analysing the market during the post-TRIPS era, it was found that the sales became more concentrated and even though there were no large increases in average pharmaceutical prices or the dramatic consolidation of the market as predicted, there was a tendency towards higher price levels in certain therapeutic segments like cancer where essentiality of patented drugs as lifesaving drugs is extremely crucial.[4] Hence, in the post-TRIPS era, it is essential that the competition in the pharmaceutical market be ensured as anti-competitive practices may have far-reaching consequences on ensuring the basic right to health and affordable medicines to all. Access to healthcare is seriously impacted by market malpractices in general and anti-competitive behaviour in the pharmaceutical and health delivery systems in particular. The three main categories of anti-competitive behaviour in the pharmaceutical industry are: related to abuse of intellectual property rights (IPRs); violations of competition laws resulting from mergers and acquisitions (M&ACQ); and collusive and other anti-competitive behaviour. The scope of this paper is limited to abuse of IPRs alone.

ANTI-COMPETITIVE PRACTICES AND ABUSE OF DOMINANCE RELATED TO IPRs

When owners of IP rights sign contracts or carry out actions that are not expressly permitted by IP statutes but appear to have anticompetitive effects, the likelihood of conflict between the application of IP statutes and antitrust statutes increase. Price fixing, abuse of power, collusive agreements, and tied selling are only a few examples of anti-competitive behaviour in the pharmaceutical industry and the health delivery system due to which medicines and health services tend to be costlier. According to Lara Glasgow, pharmaceutical companies try to extend the patent life of their brand-name medications in a number of ways, such as: (1) applying for a patent extension using legal provisions and loopholes; (2) attempting to sue generic manufacturers for patent infringement; (3) merging with direct competitors as soon as the patent rights expire in an effort to maintain the monopoly; (4) recombining pharmaceuticals

[3] Shubham Chaudhuri, Pinelopi K Goldberg and Panle Jia, "Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India," 96 *American Economic Review* 1477–514 (2006).

[4] Mark Duggan, Craig Garthwaite and Aparajita Goyal, "The Market Impacts of Pharmaceutical Product Patents in Developing Countries: Evidence from India," 106 *American Economic Review* 99–135 (2016).

slightly differently to secure fresh patents and stacking several patents on various drug components to secure perpetual monopoly rights; and (5) utilizing branding and promotion to raise the entrance barrier for generic drug makers.[5]

Common Anti-competitive conducts in the pharmaceutical industry

The current state of the pharmaceutical industry reveals an unjustified and excessive reinforcement and manipulation of intellectual property rights, which comes at the detriment of healthy competition and the well-being of consumers. The following discussion on anti-competitive practices includes a classification of each category.

Anti-competitive conduct to delay or stop generic competition

One strategy used by pharmaceutical corporations to prevent going "off-patent" is to apply for a number of patents covering various aspects of a drug over time, so that new patents take effect when older ones expire, which is known as patent evergreening. Such kinds of conduct have inescapable consequences on ensuring competition and thereby accessibility of medicines. A common anti-competitive conduct that has come before the modern competition jurisdictions for antitrust scrutiny in this context is product hopping. Product hopping is broadly characterized as a "branded manufacturer introducing a minor change to an existing prescription drug product and substantially shifting sales to the reformulated product, with the effect of inhibiting emerging competition from a generic version of the original branded product".[6] In the case *Mylan Pharmaceuticals, Inc., et al*. v. *Warner Chilcott Public Limited Corporation* (2016), it was alleged that Warner Chilcott resorted to "product hopping" by releasing three subsequent versions of its antibiotic medicine Doryx that provided consumers with little to no apparent medical benefit.[7] Each product reformulation, according to the plaintiffs in this private lawsuit, was intended to, and indeed did, obstruct substantial generic competition and protect Warner Chilcott's monopoly earnings. In an amicus brief, the Commission argued that even small, non-therapeutic modifications to branded pharmaceutical products that hurt generic competition can amount to anticompetitive conduct in violation of U.S. antitrust statutes. The Commission argued,

"The very fact of product-hopping can itself be evidence of monopoly power. The manufacturer of a brand-name drug generally undertakes a product hop to preserve

[5] Lara Glasgow, "Stretching the limits of Intellectual Property Rights: Has the Pharmaceutical Industry gone too far" *Idea- the Journal of Law and Technology* (2001).

[6] Bret Dickey and Daniel Rubinfeld, "Pharmaceutical Product Hopping: Is There a Role for Antitrust Scrutiny?" 82 *Antitrust Law Journal.* (2019).

[7] 838 F.3d 421 (3d Cir. 2016) 238 *FTC* v. *Abbvie* 976 F.3d 327 (3d Cir. 2020)

high profits that generic versions of the same drug would undercut but that no alternative drug, competing in the same market, has yet disciplined."

Knowing that their drug cannot be "off-patent" while there is active patent litigation, original brand manufacturers may resort to filing a lawsuit against generic manufacturers, alleging patent infringement on one or more "layers" of patents that have since been filed on various, frequently unimportant aspects of the drug. These along with other kinds of common sham litigations are often brought to antitrust scrutiny in the US. For instance, The Federal Trade Commission (FTC) filed a complaint in Federal District Court in 2014 alleging that AbbVie and its partner Besins Healthcare Inc. had illegally obstructed patients' access to less expensive AndroGel substitutes by bringing frivolous patent infringement claims against potential generic rivals.

The FTC was given $493.7 million in equitable monetary remedy in June 2018 after AbbVie and Besins were found accountable for filing a false lawsuit in violation of antitrust statutes[238]. Even while some of these lawsuits are undoubtedly justified, starting a legal dispute also has the added advantage of extending the time that the original brand-name medications may monopolise the market and maximising the profit for the maker.[8]

Another way that pharmaceutical companies can increase their market dominance for lucrative brand-name drugs is by using settlement agreements reached during patent infringement litigation as a cover for negotiating deals that reward generic drug manufacturers for delaying or refraining from releasing a competitor generic product. Contrary to drug firms' strategies for taking leverage of legal loopholes, the US Federal Trade Commission is increasingly challenging these agreements for violations of antitrust law. 'Patent Settlement Agreements' as they are called are any formal or informal agreement, such as a straightforward gentlemen's agreement, that resolves a current or potential patent issue. They may be referred to as a "patent settlement agreement," regardless of whether it was brought before a court or another authority or resolved outside of court without the use of a formal adversarial procedure. Patent settlement agreements are reached to settle claims in patent disputes, opposition processes, or litigation where a final ruling has not yet been issued or a judicial session has not yet taken place. A settlement agreement's main goal is to put an end to any litigation, objections, or disputes.[9]

The US FTC began looking into patent settlement agreements in 2000, believing that Abbott Laboratories and Geneva Pharmaceuticals, Inc. had entered into an anticompetitive agreement that could have delayed the introduction of generic versions of Abbott's brand-name Hytrin, a medication for high blood pressure and prostate issues. Hytrin, the brand name for the

[8] Supra note 5

[9] European Commission, "Pharmaceutical Sector Inquiry Final Report" (July 2009)

prescription medication terazosin HCL, is marketed and sold by Abbott Laboratories. Geneva and Abbott entered into a contractual agreement whereby Geneva committed to refraining from introducing any generic terazosin HCL capsule or tablet products. This commitment would remain in effect until either of two conditions were met: the resolution of the ongoing legal dispute concerning patent infringement involving Geneva's terazosin HCL tablet product, including potential review by the Supreme Court; or the introduction of another generic terazosin HCL product. In exchange for this arrangement, Abbott agreed to provide Geneva with a monthly payment of $4.5 million. Subsequently, Abbott and Geneva terminated their agreement upon becoming aware of the investigation conducted by the Commission. Due to Geneva's assurance to the FDA that its introduction of generic HCL would not violate a valid patent and its strong belief in ultimately prevailing in the patent infringement matter against Abbott, the Commission regarded Geneva as a potential competitor in the industry. In reality, Geneva was getting ready to introduce its generic terazosin HCL capsules as soon as possible in early 1998.[10]

In the case of *Federal Trade Commission* v. *Watson Pharmaceuticals Inc et a*l (*FTC* v. *Actavis*),[11] the defendants had sought regulatory approval from the FDA to market generic versions of Solvay's testosterone-replacement drug AndroGel. The companies declared in their FDA submissions that the AndroGel patent Solvay held was invalid and that their products did not violate it. The complaint claims that Solvay committed illegal acts to remove this threat after realising the disastrous impact that generic competition would have on its sales of AndroGel. The FTC claimed that Solvay gave Watson and Par a cut of its AndroGel profits in exchange for dropping their patent disputes and agreeing to postpone generic entry until 2015. The complaint claims that as a result, the defendants are working together to sell AndroGel and splitting the benefits from the monopoly rather than going head-to-head. The Supreme Court rejected decisions from lower courts that treated "reverse-payment" patent settlements as essentially free from antitrust law in June 2013. In many ways, the Supreme Court's decision in *FTC* v. *Actavis* is significant, particularly because the Court acknowledged the potential antitrust ramifications of reverse payment as a component of patent settlement agreements.

In a more recent case, *Federal Trade Commission* v. *Cephalon, Inc*.,[12] the Federal Trade Commission (FTC) initiated a lawsuit against Cephalon in February 2008. The lawsuit pertained to Cephalon's contractual agreements with four generic drug manufacturers regarding the medication Provigil (modafinil), which is used to treat narcolepsy. These contracts involved

[10] *Abbott Labs*. v. *Geneva Pharmaceuticals* 182 F.3d 1315 (Fed. Cir. 1999)
[11] 611 F. Supp. 2d 1081 (C.D. Cal. 2009)
[12] Civil Action 08-2141 (2021)

what are called "exclusion payments." All four generic companies that aimed to offer a discounted version of Provigil had entered into agreements with Cephalon. These companies had challenged the validity of the sole patent protecting Provigil from generic competition. The FTC alleged that Cephalon managed to convince these generic manufacturers to abandon their patent disputes and delay their plans to introduce a generic Provigil until 2012. This persuasion was achieved by offering them a combined sum exceeding $200 million. The Commission argued that Cephalon's strategy with these agreements had anticompetitive implications. This strategy hindered patients' access to more affordable generic versions of Provigil, resulting in consumers and other purchasers having to pay hundreds of millions of dollars extra annually for Provigil.

Antitrust law can help maintain the equilibrium between rewarding innovation and preserving competition in a number of situations, including situations like the granting of patents on minor components of outdated medications, the reformulation of obsolete medications to obtain new patents, and the use of advertising and brand name development to raise barriers for generic market entrants, where there is an abuse of the patent right by the innovative company by going beyond what is reasonably required to protect their right.[13]

Abuse of dominance

Patent-backed monopolies become a nuisance in the pharmaceutical sector in numerous ways. However, the most debated issue is that of charging exorbitant prices by dominant firms, especially in life-saving drugs. This is no longer true that because of their exclusive monopoly on the market, patented medicine costs rise, while generic drug prices stay low. Despite strict price controls in other nations, efforts to restrict the costs of patented medications have not gained much traction in the United States.[14]

Competition authorities have historically been reluctant to open investigations into high pricing, even in areas where it is regarded as an antitrust violation, such as in Europe, especially when there is no other element of abuse.[15] Excessive pricing cases have recently witnessed a growing interest of the European Commission. The Italian Competition Authority (ICA) determined in 2016 that Aspen had abused its dominant position by threatening the Italian Medicine Agency (AIFA) that it would stop supplying several of its anti-cancer drugs used in chemotherapy treatments that were deemed essential and had no therapeutic alternative in Italy if the AIFA refused to approve price increases for these products ranging from 300 to 1500%.

[13] Supra note 2

[14] Jennifer Graber, "Excessive Pricing of Off-Patent Pharmaceuticals: Hatch It or Ratchet?" 92 *New York University Law Review* (2017).

[15] Raphaël De Coninck and Elina Koustoumpardi, *Excessive Pricing Cases in the Pharmaceutical Industry: Economic Considerations and Practical Pitfalls* (www.concurrences.com, 2017).

These drugs were used in chemotherapy treatments and were considered to be lifesaving and had no therapeutic alternative in Italy. Aspen paid a €5.2 million fine to the ICA.[16] In a much earlier case, AstraZeneca was penalised by the European Commission in 2005 for allegedly abusing its dominant position, specifically by lying to various national patent offices in order to maintain or obtain additional certificates of protection for one of its highly successful gastrointestinal drugs, Losec, that it was not entitled to (or only for a shorter period of time). Because of this, generic manufacturers were unable to enter the market.[17]

Addressing the conflict: Approach of Competition enforcement Agencies

In theory, patents give pharmaceutical businesses monopoly status because, by definition, a patent gives the holder the sole right to create, use, or sell a product for a specific time. It can also be found that it is in the pharmaceutical industry, where intellectual property rights (especially patents) are stretched to their limits in an effort to maximise revenues on well-known brand-name pharmaceuticals, is perhaps where the conflict between patent and antitrust is most readily apparent.[18]

For the purpose of enforcing antitrust laws, courts and other competition enforcers treat disputes concerning intellectual property rights in the same manner as disputes involving tangible property.[19] According to the US Supreme Court, unless a claim is both objectively and subjectively without foundation, IP owners are immune from antitrust lawsuits based on the assertion of their rights under the US Constitution's First Amendment.[20]

With regard to the approaches taken by the competition enforcement authorities in specific issues of anti-competitive practices, there have been inconsistencies. For instance, the US Supreme Court had upheld a 'per se anti-competitive' approach to reverse payment settlement agreements in some cases and then reversed its position later. *In Re Cardizem Antitrust Litigation* (2003), the Circuit Court in the US held that reverse payment agreements are conclusively a horizontal agreement to limit competition in the market for the off-patent drug across the whole United States at its core, making it a prime example of a per se illegal trade restraint. The Eleventh Circuit Court later rejected the per se rule in the case of *Valley Drug Co*. v. *Geneva Pharmaceuticals Inc.*,[21] holding that these elements of the patent settlement are at the core of the patent right and cannot be used to invoke the per se label.

[16] *Incremento Prezzi Farmaci Aspen*, (2016) Italian Competition Agency Case no. 26185

[17] *AstraZeneca*, (2005) European Commission COMP/A. 37.507/F3

[18] Supra note 4

[19] Lisa Kimmel and Kate M Watkins, Intellectual Property & Antitrust (Crowell & Moring LLP, 2019).

[20] *Professional Real Estate Investors, Inc*. v. *Columbia Pictures Industries, Inc.,* (1993) 508 U.S. 49 218 F.R.D. 508 (E.D. Mich. 2003)

[21] 344 F.3d 1294 (11th Cir. 2003)

The Commission's determination In *Re Cardizem Antitrust Litigation*[22] that the agreements were immune from antitrust review if their anticompetitive effects were within the scope of the exclusionary potential of the patent was overturned by the United States Court of Appeals for the Eleventh Circuit and the appeal by the FTC against the Circuit Court was denied by the US Supreme Court.

Anti-competitive practices in the Indian pharmaceutical sector: Cases before the CCI

It is noteworthy that the Competition Commission of India (CCI) has adopted an aggressive stance against companies that use anti-competitive practices in the pharmaceutical sector. Under the Indian competition law regime, although there is an IP exemption under Section 3(5) of the Indian Competition Act that demonstrates the nation's resolute commitment to protecting IP rights in the face of competition, Section 4, which addresses the clause of abuse of dominant position, leaves plenty of room for competition interference in IP matters.[23] When viewed from an industrial standpoint, it is clear that the telecommunications industry accounts for the majority of patent-related competition lawsuits. But, in a few instances of alleged anti-competitive behaviour by pharmaceutical companies, the antitrust issue in particular has a substantial impact from a human rights standpoint. For instance, in the case of *Biocon Ltd & Others* v. *F. Hoffmann-La Roche Ag & Others* [2016], abuse of dominance was accused against the opposite party by the complainant generic manufacturer.[24] The OPs were believed to be the second largest pharmaceutical firm in the world. The Pharmaceutical business removed the original patented medicine from the Indian market in 2012 and developed Trastuzumab, a less expensive variant, in an effort to stop other competitors from creating a biosimilar version of its patented antibody and avoid the enforcement of a compulsory licence. In parallel, the informants worked together to create a less expensive biosimilar version and began producing it after being granted a licence by the Drugs Control Department of the Government of Karnataka in 2013. It was claimed by the informants that the OPs in an effort to stop the entry of new competitors in the market, began to engage in frivolous litigation against the informants after they introduced the biosimilar version on the market. Furthermore, it was alleged that the opposing parties made pointless contacts with various authorities in an effort to block the arrival of its rivals. While defining the relevant product market, the Commission interpreted Section 2(t) of the Act without accepting the OP's argument that biosimilars were not identical

[22] Supra note 21

[23] K D Raju, "The Inevitable Connection between Intellectual Property and Competition Law: Emerging Jurisprudence and Lessons for India" 18 *Journal of Intellectual Property Rights* (2013).

[24] (2016) CCI Case no. 68

to reference biological drugs, much like generics weren't identical to chemical drugs. As a result, the Commission declared that the relevant product market may include products that are "similar" in terms of their intended use; they need not always exhibit "identical" properties. In this case, "biological medicines based on Trastuzumab, including its biosimilars in India" was designated as the relevant market.

While answering the question of abuse of dominance the Commission determined that Roche Group had a prima facie dominant position in the relevant market as the allegations in the current case related to abuse of dominance beginning in 2013 (when its patent was still in effect). The Commission also noted that from 2013 to 2014 (when its patent was no longer in effect), Roche Group had a 100 percent market share. It also maintained a sizable market share and appeared to be the dominant player (in terms of both value and volume of sales) in the relevant market, despite its market share declining after the introduction of Trastuzumab's biosimilar. The informants brought forth several charges against Roche Group about abuse. The Roche Group was accused of trying to stifle competition in the market for biosimilars by engaging in frivolous legal disputes, meddling with regulatory agencies, misleading authorities, discrediting the reputation of biosimilars, etc., thereby shutting out its rivals. The Commission correctly acknowledged the peculiar structure of the pharmaceutical business; wherein to exclude market players, apart from designing pricing tactics, corporations also indulge in non-pricing techniques and try to unlawfully increase their competitors' expenses. In light of this and the potential for non-priced anti-competitive behaviour, the Commission thoroughly examined the claims. The Commission investigated whether the legal action taken against the informants by the OPs in a civil suit in the Delhi High Court was a sham litigation. The Commission responded in the negative to this inquiry, and the charge of vexatious litigation was declared to be presumptively without merit. However, with regard to the totality of the matter, the Commission held that Roche Group appeared to have engaged in a number of actions that were intended to negatively impact the market entry of biosimilars. Such measures could cast doubt on the effectiveness and safety of biosimilars due to the intrinsic nature of the pharmaceutical industry, which could have a negative impact on the market for biosimilars.

In another case *Manoj Hirasingh Pardeshi* v. *Gilead Sciences Inc*[25] [2012] before the CCI, the informants alleged abuse of dominance through exclusive voluntary licensing agreements in the matter of. In 2006, Gilead Sciences entered into non-exclusive voluntary licence agreements for the production and marketing of antiretroviral (ARV) pharmaceuticals for the

[25] (2013) CCI Case no. 41/2012

treatment of AIDS with roughly ten Indian pharmaceutical companies, including Medchem and Aurobindo. According to these agreements, licensees must pay royalties ranging from 3 to 5 percent on each finished product sold. In addition, Gilead Sciences entered into a contract in 2011 with the Medicines Patent Pool (MPP), a non-profit organisation based in Geneva, to pool rights and grant sub-licenses to pharmaceutical producers all over the world, including India. Aurobindo Pharma and Emcure Pharmaceuticals, two Indian pharmaceutical businesses, and MPP entered into tripartite arrangements on this basis.

The informant, Pardeshi had contended that a number of conditions in this agreement were anti-competitive and restricted the development and delivery of the pharmaceuticals by, among other things, requiring that they only be purchased and sold from Gilead Sciences or licensees that had been approved by it. According to the informant, the OP falsely claimed that it had been granted patents, namely 2174/DEL/98 and 01316/CHENP/2004, in the appendix to the licencing agreement with MPP, despite the fact that the Indian Patent Office website revealed that the former application was not yet published and the latter did not exist. The Commission in its order observed that the market for the production of anti-retroviral (ARV) drugs for the treatment of AIDS "was fragmented with many players engaging in the activity of production/ manufacture of ARV drugs in India" and hence there was no dominant firm in the market whose conduct may have an Appreciable Adverse Effect on Competition (AAEC) in the relevant market.

A recent decision of the CCI is of significant importance to not just Indian public health policy and law but also to the patent-competition conflict. In the case of *Swapan Dey* v. *Vifor International*,[26] the CCI dismissed a complaint against Vifor for abuse of dominance by entering into exclusive licensing agreements along with allegations of excessive pricing and price discrimination. Vifor possesses a patent for FCM injectable, a treatment for iron deficiency. The Competition Commission of India (CCI) dismissed the allegation, stating that there was no proof that Vifor's license holders could block competitors, and there were no barriers to prevent other suppliers of iron injectable from entering the market. The CCI also observed that these agreements were of limited duration, as the applicable patent would expire by 2023. The CCI indicated that discrepancies in pricing might not be discriminatory if they are grounded in a reasonable categorization of customers or if they are accessible through government procurement procedures.

[26] (2022) CCI Case no. 05/2022

In another recent ruling, the Delhi High Court addressed the question of whether the Patents Act takes precedence over the Competition Act, considering the legal principles *"generalia specialibus non derogant"* and *"lex posterior derogate priori."* Four appeals and a writ petition were lodged in 2023 with the aim of seeking clarity on a shared and impactful query. This query pertains to the scenario wherein a patent is granted in India and the patent holder asserts their rights stemming from it. The central question raised is whether the CCI can investigate the actions of such a patent holder within the scope of its authority defined by the Competition Act, 2002. The Court dismissed the proceedings initiated by the Competition Commission of India (CCI) against a patent holder due to lack of authority.[27] The Court's rationale was that patent law, being specialized legislation, should hold greater weight than the more general competition law in this context. However, it's worth noting that this perspective is not universally accepted across jurisdictions. It's important to highlight that the exception provided to Intellectual Property Rights (IPRs) under section 3(5) pertains solely to the undertaking of reasonable measures to curb infringement of one's statutory IP rights. This exception does not apply in any manner to cases involving abuse of dominance under section 4. The Ayyangar Committee report itself allows for the application of anti-monopoly statutes (formerly the Monopolies Restrictive and Trade Practices Act, 1969) in situations where a patent holder engages in abuse of dominance.[28] Therefore, despite the judicial departure from this standpoint, it can be concluded that the statutory stance in India permits competition-related intervention in instances of substantiated anti-competitive behaviour by IP holders.

Conclusion

The ruling by the Delhi High Court in the case *Telefonaktiebolaget LM Ericson* is disfavour of CCI has brought attention to the intricate interplay between the Patents Act and the Competition Act, with a specific focus on the authority of the Competition Commission of India (CCI) to investigate actions of patent holders. Competition law in its function as a market regulatory tool regulates the market in which Intellectual Property (IP) is commercialized. IP, like its literary connotation indicates, refers to certain property/assets which derive value from intellectual labour. A person who holds a patent right may exclude other competitors from selling or manufacturing his patented article, thereby reducing competition in the market. Whether the said rights exercised in this case are property rights or limited privileges is a different question altogether. However, it can be safely assumed that in today's world, whatever be its nature, IP rights are subject to competition law intervention. But this does not

[27] *Telefonaktiebolaget LM Ericson* v. *Competition Commission of India*, (2023) SCC OnLine Del 4078
[28] Justice N. Rajagopala Ayyangar, "Report on the Revision of the Patents Law" 72 (September, 1959).

mean that the rights of the IP holder may be easily compromised or written over for the sake of increasing competition in the market. There are certain safeguards in the IP statutes itself that ensures that the holders of IP do not adversely affect the competition in the market. However, these provisions alone may not be sufficient and hence, the competition statute may fill into the lacunae. While there are efforts at legislative level to identify and close the gaps and lacunas in current IP statutes, along with the competition law may be required to appropriately step in in order to curtail unfavorable business practices of the pharmaceutical industry.

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