REVERSE PATENT SETTLEMENTS IN THE PHARMACEUTICAL SECTOR: A COMPARATIVE ANALYSIS AND ROAD AHEAD FOR INDIA

Dissertation submitted in partial fulfilment of the requirements for the award of the Degree of

LL.M. (Business Laws)

to the

National Law School of India University, Bangalore

Dissertation prepared under the guidance and supervision of

Prof. Rahul Singh

Associate Professor of Law

Submitted by

NANDAKRISHNA.M

LLM/939/2020

National Law School of India University

Bangalore

SEPTEMBER 2021

SUPERVISOR'S CERTIFICATE

This is to certify that the Dissertation entitled '***REVERSE PATENT SETTLEMENTS IN THE PHARMACEUTICAL SECTOR: A COMPARATIVE ANALYSIS AND ROAD AHEAD FOR INDIA'***, submitted by Mr. Nandakrishna. M in partial fulfilment for the degree of Master of Laws of National Law School of India University, Bangalore, is the product of original and bona fide research carried out under my supervision and guidance. This Dissertation or any part thereof has not been submitted for any degree at any other university or institution.

Date:

Place: NLSIU, Bangalore Prof. Rahul Singh

DECLARATION

I, Nandakrishna.M, do hereby declare that this dissertation titled '***REVERSE PATENT SETTLEMENTS IN THE PHARMACEUTICAL SECTOR: A COMPARATIVE ANALYSIS AND ROAD AHEAD FOR INDIA'*** is the result of research undertaken by me during the course of the LL.M (Business Laws) program at National Law School of India University, Bangalore, under the guidance and supervision of Prof. Rahul Singh. I further declare that this work is original and has not been submitted anywhere for any degree at any other university or institution. Other sources of information used in the work, have been cited and acknowledged properly.

Date: 01-09-2021

NANDAKRISHNA.M

Place: MAVELIKARA I.D. No.

LLM/939/2020

ACKNOWLEDGEMENT

I feel content to state that I have received a great amount of support and assistance throughout the writing off this dissertation.

I would like to express my sincere gratitude to my teacher **Mr. Rahul Singh** whose support as a mentor and guide was invaluable at every stage of my research. His words and advices has been a guiding light for me from the preliminary stage of forming a research question and continued to the stage of analysing the key areas till reaching a conclusion. The kind of insightful feedback delivered by him at every stage pushed me to sharpen my thinking and brought my work to a better level. I pay my primary regards to him for investing in me and letting me carry out this project under his valuable counselling and direction.

I would also like to thank all my teachers at National Law School of India University, Bangalore, whose significant role in throwing light upon various intricacies in different avenues of law paved way for the development of my research idea. I'm also grateful to the to the library and IT department staff at National law School of India University, Bengaluru for their assistance in making available the relevant books and remote access to various resources for conduct of this research through their prompt assistance in this situation of pandemic

Last but not the least I extend my heartfelt gratitude to my parents and my mentor Vishnu.S.Warrier, who has been a constant support and guidance by my side.

With immense gratitude

NANDAKRISHNA.M

TABLE OF CONTENT

LIST OF ABBREVIATIONS USED

1. CCI - Competition Commission of India
2. E.U - European Union
3. E.C.J - European Court of Justice
4. FTC - Federal Trade Commission
5. MNC- Multi National Company
6. R&D - Research and Development
7. TFEU -Treaty on the Functioning of the European Union
8. TRIPS- Trade-Related Aspects of Intellectual Property Rights
9. U.S.A - United States of America

1. INTRODUCTION

Most settlements of law suits which appear to be a win-win situation for both parties, would have some serious loss allocation which is not apparent on the face of it. In the case of reverse patent settlement agreements[1] (also known as pay-for-delay agreements), it is the interest of general public which is put under jeopardy in such a seemingly win-win situation for the settling parties. They constitute one of the very recent forms of the much deliberated tussle between Competition Law and Intellectual Property Laws.

Pharmaceutical sector, which relies heavily on patent protection to recoup the substantial investment incurred in R&D has witnessed such agreements more than any others. It is often said that the prevalence of large scale information asymmetry and never-ending demand renders the idea of a rational consumer making rational choices based on prices and availability of substitutes inapplicable in the working of the prescription drug market.[2] This aggravates the need for competition law enforcement agencies to showcase exceptional vigilance so as to prevent the anti-competitive effects arising from this practice.

An ideal patent settlement scenario has two potential outcomes; either the infringer accepts the validity of the patent and infringement committed, thereby paying damages to the pioneer, or the pioneer accepting the invalidity or non-infringement and paying damages to the alleged infringer. Apparently in reverse patent settlements, two of these scenarios get combined whereby the infringer accepts the validity of the patent and damages are paid by the pioneer to the infringer.[3] Since such agreements are entered between potential rivals with an apprehended effect of output limitation and market sharing, they require serious consideration, so as to prevent any adverse implications upon consumers.[4] Courts in USA and EU have substantially dealt with multiple cases involving such settlements, adopting different standards and approaches to deal with the same. However, courts in India as well as the CCI is yet to consider a case of reverse settlement and to pronounce a judgement clarifying the approach. Considering the exponential growth of Indian pharmaceutical sector and strong

[1] These agreements are characterised by the flow of consideration from the patent holder to the alleged infringer in return for the obligation to abstain from challenging the validity of the patent which may couple with a clause for delayed entry.
[2] Competition Commission of India, *Study Report on Competition Law and Indian Pharmaceutical Industry*, (CENTAD, 2010) 5.
[3] Sven Gallasch, 'Debunking the Pay for Delay Myth: Pay for Delay Settlements Are No Ordinary Patent Settlements' (2016) 15 Competition LJ 89, 92.

patent protection awarded to inventions in line with the global standards, such agreements would essentially come-up in the near future, if not happening already.

Through this article, I intend to claim that reverse patent settlement agreements has to be considered under the category of serious restraints, and should be presumed to have appreciable adverse effects upon competition in India. I propose to put forward my claim through the following arguments;

1. Pay-For-Delay agreements has the potential to cause significant anti-competitive effects in the market.
2. The IP exemption provided under S. 3(5) of the Competition Act does not shield reverse patent settlement agreements from the purview of the Act.
3. The most favourable principle of legality to be adopted in the case of patent settlement agreements involving substantial value transfer from the incumbent to the alleged infringer would be to presume such agreements to have appreciable adverse effects upon the market.

The rationale for settlement in pharmaceutical patent disputes and the competition law implications for the same is discussed in the first two parts, followed by the vulnerability of Indian market and its place for reverse patent settlements. The applicability of Intellectual Property exemption from antitrust scrutiny in the case of reverse patent settlements is then analysed through placing reliance on USA & EU jurisprudence in this area along with the Indian jurisprudence on IP-Competition conflict. The article concludes through recommending the principles for determining the restraint of trade, which is favourable to the Indian context

2. RATIONALE FOR SETTLEMENT

Settlement of legal disputes is always regarded as a matter of sound public policy as they conserve time and limit expensive litigation.[5] In the area of patent disputes, this general need of consensual resolution of disputes is supplemented by the interests to boost innovation through optimal utilisation of resources. It is only when the motive behind a settlement is not to resolve a bona fide patent dispute but to exclude a mutual competitor of the settling parties,

[5] A Paul Heeringa, 'Dodging Antitrust Bullets in Patent Settlement Agreements: Lessons Learned from the Reverse Payment Dilemma' (2007) 5 DePaul Bus & Comm LJ 265, 297

it becomes subjected to competition law scrutiny.[6] Reverse patent settlements is considered as one such category of agreements, the basis for which is not just conservation of time and resources, but an ulterior motive of extending monopoly by disrupting competition.[7]

The peculiar nature of pharmaceutical industry, which creates competitors at two levels; being originator and generic can be regarded as the prime reason for proliferation of such agreements in this sector.[8] This sector is characterised by high cost in R&D incurred in bringing the product (drug) into the market, which is estimated to be around $1.3 billion.[9]This high sunk cost permits only a limited companies (originators) to indulge in new drug development, who would in turn recoup the expense through patent protection. Guaranteed exclusivity allows the first movers to keep the drug price way above the marginal cost of production. Once the term of patent expires, generic drug companies enter the, market with generic versions of these drugs which are bioequivalent to the patented drug. This intensifies the competition as generic drugs are priced way below the patented ones.

It has been observed that the launch prices of generics are on average 25% lower than those of brand products with existing monopoly protection, which will further drop to 40% lower after two years of launch.[10] It is estimated that, once the generics enter the market, they capture about 30% market share in volumes at the end of the first year which reaches 45% after two years.[11] EU commission report has pointed out that legal costs stemming from patent litigation in the EU relating to 68 medicines exceeded 420 million Euros in the period 2000-2007 which has increased even more now. These factors prompt originators to enter into settlements to save their monopoly.

The origin of these pay-for-delay agreements can be traced back to the Hatch-Waxman Act[12]of U.S.A, which was aimed at facilitating easier entry of generics through simplified

[6] *See* United States v. Singer Mfg. Co., 374 U.S. 174, 199-200 (1963).
[7] Farasat A S Bokhari, 'What Is the Price of Pay-to-Delay Deals' (2013) 9 J Comp L & Econ 739
[8] Michael Clancy, Damien Geradin and Andrew Lazerow 'Reverse-Payment Patent Settlements in the Pharmaceutical Industry: An Analysis of U.S. Antitrust Law and EU Competition Law' [2014]59(1) The Antitrust Bulletin. 153
[9] Olivier J Wouters, Martin McKee and Jeroen Luyten, 'Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018' (2020) 323 JAMA 844 ..
[10] European Commission 'Pharmaceutical Sector Inquiry Final Report'2009< https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf> accessed August 1, 2021.
[11] How originator companies delay generic medicines' (Generics and Bio Similar Initiative 16th December, 2011), available at < https://www.gabionline.net/Reports/How-originator-companies-delay-generic-medicines, accessed 20th May, 2021.
[12] Drug Price Competition and Patent Restoration Act, 21 USC **§355** (1984).

process.[13]Generics in most cases challenged the validity of the patent or claimed non-infringement which prompted originators to sue for infringement.[14]The Act contained provision which guaranteed 180 days exclusivity for the first generic challenger[15] which incentivises the originator to strike a deal to exclude further competition.

The EU Commission's pharmaceutical market inquiry found a total of 200 patent settlements in the period, out of which 99 agreements contained some kind of value transfer from the originators to the generics.[16] Out of these 99 agreements, 44 agreements included value transfer in the form of lump sum payment.[17] These statistics read along with the number of cases brought before the commission signifies that pay-for delay agreements are not limited to the Hatch-Waxman framework.

3. IMPLICATIONS UPON COMPETITION

The general arguments in favour of settlements in the nature of procedural efficiency and conservation of resources does not come to rescue when there is a payment in the reverse direction. The advantage conferred by virtue of patents should act in favour of the pioneer in a patent infringement suit under normal conditions. The opposite poses a genuine question towards its implications. As Shapiro observes, 'Presumably, the patent-holder would not pay more than avoided litigation costs unless it believed that it was buying later entry than it expects to face through the alternative litigation.'[18]

Such a later entry has serious consequences on consumer welfare in the form of increased drug prices, something which competition law intends to prevent. When generic entry occurs, consumers begin to benefit immediately from the savings associated with lower generic drug prices. Following the initial entry period, the generic market expands and consumer starts receiving advantages in the form of savings by virtue of the generic competition. Thus any delay caused will result in significant loss for the consumers as they are prevented from the benefit of competitive prices. The Federal Trade Commission, the primary antitrust enforcement agency in U.S.A has estimated that pay-for-delay settlements have delayed

[13] See, Section 505(j) of the Act, codified as 21 U.S.C. § 355(j) which provides for Abbreviated New Drug Application(ANDA), for approval by FDA
[14]Mark William Murphy, 'Red Flag or Red Herring: Reverse Payments and the Settlement of Pharmaceutical Patent Litigation' (2008) 4 Eur Competition J 541
[15]See, 6.21 U.S.C.A. § 355(j)(5)(B)(iv)
[16] The Final Report by the European Commission on the Pharmaceutical Sector Inquiry dated 8 July 2009, Para 758.
[17] Ibid.
[18] Carl Shapiro, 'Antitrust limits to patent settlements' [2003] 34 (2), RAND Journal of Economics 391,408.

generic entry by an average of 17 months at a cost to the consumer of savings totalling US$3.5 billion for the period from 2004 to 2009. [19]

In fact, if an incumbent pays a generic for later entry of its bio-equivalent drug, there must be some counterweighing consideration in the form of a collusive agreement to divide the market.[20] Such agreements to delay entry, entered between competitors, under normal circumstances, come under the category of horizontal market allocation, which competition authorities around the globe regard as a serious anti-competitive conduct.[21]

A study conducted by FTC in revealed that generic manufacturers have prevailed in 73 per cent of challenges against the brand name drug owner, in matters computed over a decade.[22] This actually points to the weakness of patents held which can one of the main reasons for the originators to settle. Advocate-General M.Darmom of ECJ in *Bayer v Süllhöfer*, a case dealing with the licensing terms containing provision for refraining from challenging the industrial property, has observed that 'If the patentee agrees to an amicable settlement, thereby accepting in part his adversary's claims, his right is unlikely to be of the unchallengeable nature required by the hypothesis.'[23]

In cases of significant reverse payments, the pioneer actually exchanges the uncertainty for the certainty that the generics would abstain from entering the market. [24]This would inevitably, affect dynamic competition by precluding innovation. This is evident from a having a broader market outlook assessing its effect not only on innovation by originators, but also on follow-on innovation by generic companies.[25]This problem is further aggravated by the fact that, despite the alleged surge in investments into pharmaceutical R&D, current

[19] Federal Trade Commission 'Pay-for-delay: how drug company pay-offs cost consumers billions', FTC staff study (2010).
[20] Supra Note 14, 545.
[21] See, S.3(3) Competition Act, 2002, Article 101(1) of Treaty on the Functioning of the European Union ('TFEU'), Section 1 Sherman Antitrust Act 1890, 15 U.S.C. § 1 which provides presumption of anti-competitiveness for horizontal agreements.
[22] Federal Trade Commission, 'Generic Drug Entry Prior to Patent Expiration: An FTC Study' (2002) 13.
[23] Case 65/86 *Bayer v Süllhöfer* [1988] ECR 5249.
[24] Amalia Athanasiadou, 'Lundbeck v. Commission: The First Decision of the European General Court on Reverse Payments' 2016, Jusletter < https://www.researchgate.net/publication/316437908_Lundbeck_v_Commission_The_First_Decision_of_the_European_General_Court_on_Reverse_Payments> accessed 4th August,2021
[25] Olga Gurgula, 'Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?' (2020) 51 IIC - International Review of Intellectual Property and Competition Law 1062.

statistics indicates a decreasing trend in number of breakthrough drugs.[26] All these factors point towards a serious antitrust issue which demands adequate consideration.

4. HOW VULNERABLE IS THE INDIAN MARKET?

It is true that the Indian competition law regime, relatively at a nascent stage is yet to produce any substantial jurisprudence on pay-for-delay agreements. However, a comprehensive understanding of its pharmaceutical sector would suggest that high possibility of such agreements can't be ruled out. India's implementation of its commitment under TRIPS[27] agreement to recognise product patents in the year 2005 resulted in a rise in patent applications, filed mostly by foreign pharma giants. This challenged the autonomy of India's peculiar 'branded generics'[28] who ruled the market from 1970s by way of reverse engineering. As we approach the years of expiry of most of those patents, chances for reverse settlements by originators are quite high.

The phenomenon of branded generics also adds to this probability by virtue of the existence of limited number of generic firms capable of bringing the generic alternative, which the originator needs to take care of. It is estimated that branded generics alone constitutes around 90% of the total sales of pharmaceutical products in India.[29]

This should be read in conjugation with the exponential growth in the pharmaceutical sector predicted for the coming years. As per the Indian Economic Survey 2021, the domestic market is expected to grow 3x in the next decade.[30] India's domestic pharmaceutical market which is estimated at US$ 42 billion in 2021 is predicted to reach US$ 65 billion by 2024 and further expand to reach US$ 120-130 billion by 2030.[31] The fact that India will remain a lucrative market will further enhance the chance for originators to adopt strategies to protect

[26] Ibid
[27] See, Article 27, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization (WTO) (1994), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).
[28] Branded Generics are either novel dosage forms of off-patent products produced by a manufacturer that is not the originator of the molecule, or a molecule copy of an off-patent product with a trade name which after being continuously prescribed by physicians, get a status near to the original brand.
[29] Confederation of Indian Industries *'India Pharma Inc.: Capitalising on India's Growth Potential'* (2010) Pharma Summit< https://www.pwc.in/assets/pdfs/publications 2011/pwc_cii_pharma_summit_report_22nov.pdf> accessed 11th August, 2021.
[30] Indian Brand Equity Foundation, 'Indian Pharmaceuticals Industry Analysis' 2021< https://www.ibef.org/industry/indian-pharmaceuticals-industry-analysis-presentation>, accessed 10th August 2021.
[31] Ibid

their monopoly. Large scale acquisitions of local players by large MNCs (often originators) through mergers and acquisitions elucidates this trend.[32]

5. PAY-FOR-DELAY IN THE INDIAN CONTEXT: WHERE DOES IT FIT IN?

Section 3 of the Competition Act, 2002 renders void any agreement, in respect of production, supply, distribution, storage, acquisition or control of goods or provision of services, which causes or is likely to cause an appreciable adverse effect on competition. Pay-for-delay agreements are entered into between originator and a generic firm which the former considers as its most potent competitor. Such agreements in India, are considered under the purview of 'horizontal agreements' which is specifically dealt with under Section 3(3) of the Indian Competition Act, 2002.[33] This section regulates any agreement entered into between persons engaged in identical or similar trade of goods or provisions of services.

The mere fact that the generic has not begun commercial exploitation of their version of the drug, won't be an embargo in regarding them as direct competitors. The Competition Commission of India (CCI) in Sugar Mills case,[34] has observed that "*the phrase 'is engaged in' also includes 'not merely projects which have been completed and gone into production but also blueprint stages, preparatory moves and like ante-production points.*"

The section contains a list of conducts though a horizontal agreement which is presumed to have an appreciable adverse effect upon competition. This includes price fixation, output limitation and market sharing. Pay-for- delay agreements in most cases have either of these consequences. Through delaying generic entry, the high price is more-or less fixed for an extended period of time. In fact, the emergence of a set of jurisprudence around the globe shows that it is not just blatant price fixing that is caught, but also any agreement that might directly or indirectly suppress price competition.[35] Also, such agreements directly limits the output by thwarting generic entry thereby depriving the consumers of substitutability. Patent

[32] Business Today "Large merger and acquisitions back in Indian pharma" < https://www.businesstoday.in/industry/pharma/story/large-merger-and-acquisitions-back-in-indian-pharma-90416-2017-11-06>, accessed 14th August, 2021.
[33] Section 3(3). Competition Act, 2002.
[34] In Re: Cartelisation in Sale of Sugar Mills **by** the Uttar Pradesh State Sugar Corporation Limited **(**UPSSCL) and the Uttar Pradesh Rajya Chini Evam Ganna Vikas Nigam Limited **(**UPRCGVNL**),** Suo Moto Case No. 01 of 2013.
[35] Supra Note 2, 11.

settlement agreements containing reverse value transfers in the form of side-deals[36] or territory allocation would essentially fall within the category of horizontal market sharing among competitors.

6. DOES THE EXISTENCE OF IP RIGHT ACT AS A SHIELD AGAINST ANTITRUST SCRUTINY?

Presence of patents held by originators in pay-for-delay agreement questions the applicability of competition law as most antitrust regimes across the globe has provided certain kind of exemption for holders of IP rights in their exercise of such rights, considering the need to maintain dynamic competition.

In EU and USA, there are no explicit legislative immunities in the competition rules of Articles 101 and 102 of the European Treaty or Sections 1 and 2 of the Sherman Act. Such immunities in both legal systems have been given though judicial and administrative interpretations[37] However, Indian law in contrast, contains specific provision within the act to address the interface.

1. Position in U.S.A

Legislative guidance in the area of protection of IP rights from antitrust scrutiny in U.S.A is present in the form of 'safety zones' in FTA's antitrust guidelines.[38] Such safety zones are applicable based on two conditions

1. The restriction imposed must not *prima facie* be anti-competitive; and
2. The market share of the licensor and the licensee must not collectively exceed twenty percent of each market that such a restriction is impacting.[39]

However, in none of the cases involving a reverse payment for settling a patent disputes, the courts in USA relied on the safety zones for granting immunity.

[36] Value transfers of this nature was identified in decision of the European Commission in *Perindopril (Servier)* (Case AT 39612) [2014] OJ 2016 C 393/7.
[37] Steven D. Anderman, *The Interface Between Intellectual Property Rights And Competition Policy* (Cambridge University Press, 2007)
[38] FTC, Antitrust Guidelines for the Licensing of Intellectual Property, January 2017https://www.ftc.gov/system/files/documents/public_statements/1049793/ip_guidelines_2017.pdf, accessed 15th August, 2021.
[39] Ibid.

The Eleventh Circuit Bench of U.S.A applied the 'the scope of patent' test, which relied on the exclusionary power of the patent to determine the anti-competitiveness of an agreement in the case of Schering-Plough Corp[40] The court observed the terms of the settlement which involved a reverse payment to be within the patent's 'exclusionary power' and therefore a 'reasonable implementation' of the protections afforded by patent law.[41]

However, subsequent decision of the Third Circuit in *re Kdur Antitrust Litigation*[42]disregarded this test and stated that "by endorsing settlements that protect weak patents, the scope of the patent test would undermine the objectives of the Hatch-Waxman Act to increase the supply of affordable drugs through generic challenges."

The conundrum was finally settled in *Actavis case*[43], where the also rejected scope of patent test. Court pointed towards the absence of patent validity in such disputes. It was observed that, '*the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.'*

2. Position in E.U

Safe harbours for the exercise of IPRs in EU has been developed in the form of block exemptions as an extension of Article 101 of the Treaty on the Functioning of the European Union (TFEU). The Technology Transfer Block Exemptions[44], alike its U.S counterpart entails market share is a crucial determinant of the operation of safe harbours or reasonable conditions. They also create a clear demarcation between horizontal and vertical competition for determining the applicability of safe-harbour provisions, the latter being favoured for its applicability. Hence, it can be assumed that pay-for-delay agreements which is of the nature of horizontal market division is least likely to be within its purview.

The argument for application of 'scope of patent' test was put forward by the applicants in the well-known *Lundbeck's*[45] case. It was asserted that agreements containing restrictions inherent to the exercise of patent rights should not be covered by Article 101(1) TFEU.

[40] Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005).
[41] Ibid
[42] 686 F.3d 197 (3rd Cir. 2012).
[43] FTC v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013).
[44] Commission Regulation (EU) No 316/2014 of 21 March 2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements, OJ L 93, 28.3.2014, https://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX%3A32014R0316, accessed 14th August, 2021.
[45] Case T-472/13, H. Lundbeck A/S and Lundbeck Ltd v European Commission,EU:T:2016:449,

Anyhow the restriction in the said case was beyond the term of patent. Still an important observation was made by the commission that '*even if the restrictions imposed by the settlement agreements potentially fell within the scope of the relevant patents, these agreements went beyond the subject matter of the IP rights; this subject matter includes the right to oppose patent infringements but not the right to pay actual or potential competitors in order for them not to enter the market.*'[46] Thus the argument of scope of patent was clearly rejected.

3. Effect of S.3(5), Competition Act in the Indian Context

Experiences from foreign jurisdictions in this matter suggests that pay-for-delay agreements being more serious nature of licensing agreements does not qualify for a blanket exemption from antitrust scrutiny. Statutory exemption for IP rights within the legislation raises doubt in its adoption.

S. 3(5) of the Competition Act, 2002 is intended exempt the right of any person to restrain any infringement of, or to impose reasonable conditions, as may be necessary for protecting any of his rights granted under relevant IP statute. However, this shall not be considered as a blanket exemption.

CCI in *FICCI – Multiplex Association of India* v. *United Producers/ Distributors Forum*[47], has clarified that the non-obstante clause in §3(5) of the Act is not absolute and that the exemption is only to protect their rights from infringement. CCI here clearly distinguished 'protection' from 'commercial exploitation', and laid down that §3(5) would be applicable only in case of the former.

In the *Shamsher Kataria's* case[48], CCI noted that the existence of an IPR does not entitle the right holder to avail the exemption; a condition should be both reasonable and necessary for the protection of certain IPR in question. CCI in this case interpreted *necessary* to mean indispensable for the protection of IPRs. The term 'reasonable conditions' is not defined in the Act. However, the Commission published 'An Advocacy Booklet on Intellectual Property Rights', where it was stated that arrangements likely to affect adversely the prices, quantity,

[46] Ibid, Para 495,539
[47] 2011 SCC Online CCI 33.
[48] Shamsher Kataria v. Honda Siel Cars India Ltd 2014 SCC OnLine CCI 95

quality or varieties of goods and services will fall within the contours of competition law as long as they are not within the bundle of rights that go with IPRs.[49]

Commission proposed 3 pronged test to determine the applicability of immunity.

"a. Whether the right which is put forward is correctly characterized as protecting an intellectual property;

b. Whether the requirements of the law granting the IPRs are in fact being satisfied; and

c. Whether the IPR holder would be able to protect his IPR, even if such restriction was not present"[50]

Considering these factors, it is clear that pay-for-delay agreements are least likely to be protected under S. 3(5) of the Act as the right to delay the entry of the potential infringer by making payments is not a statute conferred right. In the absence of any presumption as to the validity of patent under the Patent's Act,[51] reverse payments cannot be considered as a reasonable act intended for protection of rights.

7. WHAT SHOULD BE THE IDEAL APPROACH?

As the anti-competitive potential of pay-for delay agreements has been established, the next step is to determine the principle to be adopted to determine its legality. The framework provided by Competition Act, 2002 sets out two broad methods of analysis;

a. Per-se Rule[52] (Which considers agreements to be presumptively un-lawful unless pro-competitive effects is shown by the party)

b. Rule of Reason[53] (Which considers agreements as un-lawful only if appreciable adverse effects upon competition is proved)

U.S and E.U authorities has also arrived at somewhat similar standards to assess pay-for-delay agreements.

1. Rule of Reason

[49] 'Advocacy Booklet on Intellectual Property Rights' Competition Commission of India, available at https://www.cci.gov.in/advocacy-booklet/126, accessed on 04 August, 2021.
[50] Ibid.
[51] As clarified by the Gujarat High Court in Cadila Pharmaceuticals Ltd., v. Instacare Laboratories Pvt. Ltd. 2001 PTC 472 (Guj).
[52] Applied in the case of horizontal agreements. See, S. 3(3), Competition Act, 2002.
[53] Applied in the case of vertical agreements. See, Ibid S 3(4), S. 19(4).

The U.S Supreme Court applied the rule-of-reason analysis for reverse patent settlements in *Actavis case*[54]. The terms in the agreement included the commitment by the generics not to enter the market before a few years to the patent expiry, to co-promote the patented drug and payment of a large sum in return. The court opined that the situation where anti-competitive effects is remarkably evident for the per-se rule to be applicable were absent here. It was also observed that early generic entry through settlement would be beneficial to customers. Factors including the size of the reverse payment, its scale in relation to the payer's anticipated future litigation costs etc. were listed out to be considered while applying rule of reason.

2. Per-se Rule

As per the general rule, horizontal agreements among competing sellers to fix prices or restrict output are, absent more, per se violations of Section 1 of the Sherman Act.[55] Various circuit benches of U.S, relying on this proposition had applied per-se rule with regard to pay-for-delay agreements.[56] The decision of the EU Commission, which were later upheld by the CJEU, in *Lundbeck*'s case[57] held pay-for-delay agreements as restriction of competition by object, under Article 101(1) of TFEU. The terms in the settlement included non-challenge clause for a period in excess of patent expiry. This rule is more or less similar to the per-se rule, in the sense that no further anti-competitive effect has to be proved against the defendant in such cases. The court held that that collusion and co-ordination among the innovator drug and the generics amounted to 'buying-off' of potential competition. It was highlighted that the size of the reverse payment is an indicator of the strength or the weakness of a patent and the pay for delay agreements do not warrant assessing the validity of a patent.

In India, Competition Act, 2002 classifies the principles of legality in assessing a restraint into two categories depending on where the burden of proof is attached. Agreements among competitors, considered to be restraints of a serious nature is presumed to be having appreciable adverse effects on market, where the burden of proof is upon the party to prove the contrary. Agreements among enterprises at different levels at the market, considered to cause lesser restraints is considered as anti-competitive only if the appreciable adverse effects or possibility for the same is proved by the enforcer. Analysis of the two different

[54] 686 F.3d 197 (3rd Cir. 2012).
[55] Athletic Ass'n v. Bd. of Regents of the Univ. of Okla, 468 U.S. 85, 100 (1984))
[56] See In re Cardizem CD Antitrust Litigation, 332 F.3d 896 (6th Cir. 2003), Terazosin, 352 F. Supp. 2d at 1310.
[57] Supra Note 44

approaches and its justifications in foreign jurisdictions considered along with the ground realities in the Indian pharmaceutical sector would favour adoption of presumed appreciable adverse effects in case of reverse patent settlement agreements. This approach rests on the logic that the mere payment from a brand name manufacturer to a generic drug manufacturer for agreement by the latter to delay its market entry for such consideration, serves as a *prima facie* evidence of unreasonable restraint of trade. First of all, the statutory framework for competition law, as well as the judgements rendered by CCI is clear and consistent in adopting the principle of presumed appreciable adverse effects for horizontal agreements. The question of agreement with potential competitor to be horizontal in nature being already settled[58], the said approach would result in direct application of the settled principle.

The pro-competitive justification provided in *Actavis*[59], in the form of early generic entry due to settlement does not hold good considering the non-existence of presumed validity of the patent. This is because, in case the litigation result in invalidity of the patent, generic entry would have been possible even at an earlier stage. Thus, consent to an early entry may also point towards weakness of the patent held. Also, a case by case analysis, considering the value of payment as suggested by U.S Supreme Court, without a clarity to the threshold value would create hurdles in practical implementation, especially in India where the regime is in its nascent stage. The lesser competence of CCI when compared to FTC may also impact gathering of evidence to prove appreciable adverse effects, in case rule of reason is adopted.

Also, U.S regards IP rights in a much higher sacrosanct and have historically been afforded with a higher protection against antitrust scrutiny.[60] Also, other policies, apart from the ones strictly related to IP Law and Competition Law are rarely considered by courts there. However, Indian scenario is different as the ensuring viable access to health treatments and limiting public expenditure on health has always been the top policy consideration here.[61] Lenient application of compulsory licensing[62] as well as statutory safeguards[63] incorporated against strategic patenting substantiates this intent.

[58] Supra Note 33.
[59] Supra N 42.
[60] KOBAK J.B.,' Running the Gauntlet: Antitrust and Intellectual Property Pitfalls on the two Sides of the Atlantic', (1996) 64 Antitrust Law Journal 353
[61] This is evident by the legislative as well as judicial approaches in effectively implementing every exemptions provided under TRIPS so as to minimise the burden upon general public.
[62] See Bayer Corporation v. Union of India 2014 SCC Online Bom 963
[63] See S. 3(d), S. 107 A (a), S.92.A, Patents Act, 1970.

8. CONCLUSION

Despite being known as the 'pharmacy of the world', millions of Indian households still lack access to vital drugs.[64] The fact that 69% of the total health expenditure in India is accounted by out of pocket expenditure shows the necessity to maintain drug prices at affordable levels.[65] Competition law has a vital role to play in this regard through keeping a check on the practices employed by firms in the pharmaceutical sector. Pay-for-delay agreements constitute one of the most serious forms of horizontal agreements which has a great potential to cause appreciable adverse effect upon completion. While there have been reports of CCI monitoring certain settlements including the one concluded between Cipla and Roche,[66] no case has been initiated yet.

Presence of considerable number of patents awaiting expiry in the coming years along with the presence of branded generics with significant market share makes Indian market vulnerable to such agreements. Mere existence of patent right does not exempt such agreements from the purview of competition law as it is the reasonable exercise of such right which is protected under law. The legal principle to be taken on reverse patent settlements is very much crucial as it has direct implications upon affordable health care. Adopting a principle which is too permissive, would lead to risk allowing competitors to collude and make it difficult for the CCI to prove the violation. Hence, under the Indian scenario, presumed appreciable adverse effects upon competition would be the most suitable approach to be taken for pay-for-delay agreements. The settling parties are not adversely affected through this approach as they can rebut this through pro-competitive benefits under S. 19(3). This approach also creates legal certainty and allows all market participants to adapt their conduct accordingly.

In order to act as an additional check, mandatory settlements of all patent settlements, at least in the pharmaceutical sector[67] can be implemented so that CCI gets first-hand information regarding such settlements. This would act as a deterrent against settlements of anti-competitive nature.

---

[65] Government of India, National Health Accounts Technical Secretariat, National Health System Resource Centre, Ministry of Health and Family Welfare, National Heath Accounts-estimates for India

[66] Twinkle Chawala and Ruchi Verma, 'Pay for Delay Agreements: Antitrust Watch Intensifies' (2018) 5 J Nat'l L U Delhi 22, 23.

[67] As implemented in U.S under Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

9. BIBLIOGRAPHY

PRIMARY SOURCES

A. PRIMARY LEGISLATIONS

1. Competition Act, 2002
2. Patent Act, 1970.
3. Sherman Antitrust Act, 1890
4. Drug Price Competition and Patent Term Restoration Act, 1984.
5. Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).
6. Consolidated versions of the Treaty on the Functioning of the European Union (TFEU) [2016] OJ C202/1.
7. Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994.

B. SECONDARY LEGISLATIONS

1. FTC Antitrust Guidelines for the Licensing of Intellectual Property, 2017.
2. Commission Regulation (EU) No 316/2014 of 21 March 2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements, OJ L 93, 28.3.2014.
3. CCI Advocacy Booklet on Intellectual Property Rights, 2015.

C. REPORTS

1. Competition Commission of India, Study Report on Competition Law and Indian Pharmaceutical Industry, CENTAD, 2010.
2. European Commission Pharmaceutical Sector Inquiry Final Report, 2009.
3. Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study 2002.

D. CASES

1. United States v. Singer Mfg. Co., 374 U.S. 174, 199-200 (1963).
2. Bayer v Süllhöfer Case 65/86 [1988] ECR 5249.
3. Re: Cartelisation in Sale of Sugar Mills **by** the Uttar Pradesh State Sugar Corporation Limited **(**UPSSCL) and the Uttar Pradesh Rajya Chini Evam Ganna Mkas Nigam Limited **(**UPRCGVNL**),** Suo Moto Case No. 01 of 2013.
4. Re Kdur Antitrust Litigation 686 F.3d 197 (3rd Cir. 2012).

5. Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir. 2005).
6. FTC v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013).
7. H. Lundbeck A/S and Lundbeck Ltd v European Commission, Case T-472/13, EU:T:2016:449.
8. Shamsher Kataria v. Honda Siel Cars India Ltd 2014 SCC OnLine CCI 95
9. FICCI – Multiplex Association of India v. United Producers/ Distributors Forum 2011 SCC Online CCI 33.
10. Cadila Pharmaceuticals Ltd., v. Instacare Laboratories Pvt. Ltd. 2001 PTC 472 (Guj).
11. Athletic Ass'n v. Bd. of Regents of the Univ. of Okla, 468 U.S. 85, 100 (1984).
12. Re Cardizem CD Antitrust Litigation, 332 F.3d 896 (6th Cir. 2003).

SECONDARY SOURCES

A. BOOKS

1. Steven D. Anderman, 'The Interface Between Intellectual Property Rights And Competition Policy' Cambridge University Press, 2007.
2. Richard Whish & David Bailey, 'Competition Law' 7th Edition, Oxford University Press, 2012.

B. ARTICLES

1. Sven Gallasch, 'Debunking the Pay for Delay Myth: Pay for Delay Settlements Are No Ordinary Patent Settlements' Competititon Law Journal 2016.
2. Paul Heeringa, 'Dodging Antitrust Bullets in Patent Settlement Agreements: Lessons Learned from the Reverse Payment Dilemma' DePaul Business & Commercial Law Journal 2005.
3. Farasat A S Bokhari, 'What Is the Price of Pay-to-Delay Deals' Journal of Competition Law & Economics 2013.
4. Michael Clancy, Damien Geradin and Andrew Lazerow 'Reverse-Payment Patent Settlements in the Pharmaceutical Industry: An Analysis of U.S. Antitrust Law and EU Competition Law' The Antitrust Bulletin, 2014.
5. Olivier J Wouters, Martin McKee and Jeroen Luyten, 'Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018' Journal of American Medical Association.
6. Mark William Murphy, 'Red Flag or Red Herring: Reverse Payments and the Settlement of Pharmaceutical Patent Litigation' Eur Competition Journal 2008.

7. Carl Shapiro, ‘Antitrust limits to patent settlements’ RAND Journal of Economics, 2003.
8. Olga Gurgula, ‘Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?’ International Review of Intellectual Property and Competition Law, 2020.
9. KOBAK J.B., ‘Running the Gauntlet: Antitrust and Intellectual Property Pitfalls on the two Sides of the Atlantic’, Antitrust Law Journal 1996.
10. Twinkle Chawala and Ruchi Verma, 'Pay for Delay Agreements: Antitrust Watch Intensifies' Journal of National Law University Delhi, 2018.