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## REVERSE PAYMENT PATENT SETTLEMENTS: NAVIGATING THE ANTITRUST LIABILITY IN THE PHARMACEUTICAL INDUSTRY

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*Affordable healthcare is the foremost policy objective of states and it is generally determined by the quality of drugs available in the market and the reasonableness with which they are priced. In turn, the success of this objective principally depends on the factors which govern a pharmaceutical industry such as, the costs incurred in research and development of new drugs, the validity of patents on new drugs and the revenue generated from their exclusive exploitation. These factors often prompt the innovator drug companies to pay off their generic counterparts to avoid stiff competition from them in the drug market and maintain market exclusivity beyond what the term of their patents permits. Given the constant interaction of Intellectual Property Rights and Competition law in the pharmaceutical sphere, such pay offs or rather settlements have drawn the attention of the competition authorities from across the globe which are now vehemently scrutinizing the behavioral abuse by drug companies and the anti-competitive nature of the pay for delay settlements agreed between them. A quick glance makes it sufficiently apparent that when the healthcare of consumers at large is concerned, the exclusivity offered by patented drugs cannot be unreasonably stretched for unilateral profit motives of drug companies.*

### ***I. INTRODUCTION***

Have you ever wondered the repercussions that would follow if all the medicines and drugs available in the market were excessively priced? Regardless of policy differences, ‘affordable healthcare’ is often regarded as a primary objective by all States alike and the same is evident from the significant percentage of their budgets that is allocated to the healthcare sector year on year. However, in an industry where medicines and innovations are concerned, the factors that actually assist in achieving this objective are heavily influenced by the nature and dynamics of the said industry. Given the costs involved in the research and innovation required in developing new drugs, pharmaceutical companies have to ensure that their inventions are successfully patented so that they can recoup the costs and generate revenue by exercising the exclusive right to manufacture, market and sell the patented drug until the patent expires.

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Broadly speaking, the domain of pharmaceutical drugs consists of a brand drug, which is the high-priced patented invention of the innovator drug company, and a generic drug which chemically resembles the brand drug in dosage and strength but is low-priced and does not enjoy patent protection. A drug market is characterized as one which encompasses both the brand and the generic variations of a drug where both majorly compete on the factor of price, and the availability of generic drugs immensely assists in providing affordable healthcare to the consumers at large.

A peculiar trend typically associated with the pharmaceutical industry is the rise in *pay for delay* agreements where essentially the brand drug company or originator company (patentee) pays off a significant sum to the generic drug company (potential competitor/possible patent infringer) to delay the entry of the low-priced generic drug in the market, thereby prolonging the exclusivity period enjoyed by the brand drug in the drug market. These agreements commonly arise in the form of out-of-court settlements resulting from patent infringement lawsuits between the brand and generic drug companies and are frequently referred to as reverse payment agreements, as they signify a total spin of payments where money flows in the opposite direction, as opposed to the ordinary course where a patent infringer compensates the patentee.

Needless to say, such payments not only contribute to the trend of ever-greening of patents by virtually extending the legal validity period of a patented drug, but also adversely affect the drug competition by creating market-exclusivity, supra-competitive prices and restricting competition from generic competitors. It is this interaction of Intellectual Property Rights (“**IPRs**”) and Competition Law, a persistent conundrum of patent exceptionalism and antitrust scrutiny that has raised the fundamental question of the legality of reverse payment agreements in many jurisdictions.

This paper is a comparative study of the regulatory and judicial approach adopted by the United States of America (“**U.S.**”), which has finally settled the law on the legality of reverse payment agreements and the European Union (“**E.U.**”), which has only recently authoritatively addressed the issue by taking a squarely different stance. Given the contrasting approaches on either side of the Atlantic, the authors attempt to address the issue from an Indian perspective..

## *II. POSITION IN THE U.S.*

When one attempts to explore the origin and legality of reverse payment agreements in the pharmaceutical industry of the U.S., there are two crucial aspects which require examination – *first*, the giant size and profit oriented nature of the pharmaceutical industry<sup>1</sup> and *second*, the Drug Price Competition and Patent Term Restoration Act of 1984 (“**Hatch Waxman Act**”). This part seeks to examine the regulatory framework effective in the U.S. that inadvertently fuels reverse payment settlements and will go on to analyze the judicial approach in determining the legality of such settlements.

### *A. REGULATORY FRAMEWORK: HATCH WAXMAN ACT AND PARAGRAPH IV LITIGATION*

While the legislative intent behind enacting the Hatch Waxman Act was to encourage entry of generics into the market and promote medical innovation by directing the cost savings to the development of new drugs, it is often disheartening to discover that reverse payment agreements were stimulated by the drug companies as a response to these very goals.<sup>2</sup>

In essence, the Hatch Waxman Act created an abbreviated passage for the approval and marketing of generic drugs wherein generic companies were required to file an Abbreviated New Drug Application (“**ANDA**”) to the Food and Drug Administration (“**FDA**”) detailing that the generic drug manufactured by them was the bioequivalent of its brand name drug counterpart and consisted of the same active ingredients which had already been approved by the FDA.<sup>3</sup>Inferably, the rationale behind the ANDA procedure was to save costs and avoid engaging in the time consuming testing and approval of generic drugs to help pace up their entry into the market, thereby ensuring drug competition and availability of low cost generic drugs to the consumers.<sup>4</sup>

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<sup>1</sup> Chris Lo, *Drug Prices: Profits Before Patients?*, PHARMACEUTICAL-TECHNOLOGY.COM, (June 9, 2014), <http://www.pharmaceutical-technology.com/features/featuredrug-prices-profits-before-patients-4285101/>.

<sup>2</sup>*A CBO Study: How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, THE CONGRESS OF THE UNITED STATES CONGRESSIONAL BUDGET OFFICE, 14 (July, 1998), <https://www.cbo.gov/sites/default/files/pharm.pdf>.

<sup>3</sup>*Abbreviated New Drug Application (ANDA): Generics*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics> (last updated April 8, 2016).

<sup>4</sup> *Generic Drugs: Questions and Answers*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm> (last updated July 1, 2015).

***B. LEGALITY OF REVERSE PAYMENTS: THE U.S. WAY***

As wise as the objects of the Hatch Waxman Act may have been, the pharmaceutical industry in the U.S. was even wiser to quickly apprehend the downside of a patent infringement litigation which included exorbitant litigation expenses, delayed proceedings and related costs, which cumulatively had the potential to significantly diminish the investments otherwise meant for new drug research.<sup>5</sup> In addition, in the likelihood of the challenged patent's being declared invalid, it would open the floodgates for generic drug companies to enter the market and bring down the revenues of the brand drug company.<sup>6</sup> The potential loss of revenue is even more potent when the drug in question is a significant one or a runaway success.<sup>7</sup> Thus, as a response to what the Hatch Waxman Act sought to achieve, the parties involved in litigation resorted to patent infringement settlement agreements, now generally referred to as reverse payment agreements, where the brand drug company would not only drop the lawsuit, but would also pay the generic drug company to delay its entry into the market.<sup>8</sup>

It did not take the Federal Trade Commission (“**FTC**”) very long to ascertain how the terms of such settlements were not only anti-competitive but were also undermining the broad objective of affordable healthcare.<sup>9</sup> The FTC investigations into these settlements quickly opened the Pandora's Box for antitrust litigation where drug companies now found themselves in violation of antitrust laws, struggling to address the very legality of reverse payment agreements which they had entered into in the first place.<sup>10</sup> The Sherman Antitrust Act of 1890 (“**Sherman Act**”) aims to prevent anticompetitive practices and protect competition as the rule of trade.<sup>11</sup> It contemplates two kinds of breaches – a *per se* breach,<sup>12</sup> which does not require any inquiry into the effect or intention behind

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<sup>5</sup> Mark G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 ANTITRUST L.J. 3, 1039-1040 (2004).

<sup>6</sup> Steven Seidenberg, *The Flip Side of 'Reverse Payments': Can Patent Holders Buy Off Infringers? Courts Take Another Look*, 96 ABA Journal 2, 17-18 (2010).

<sup>7</sup> *Id.* at 18.

<sup>8</sup> James Langenfeld and Wenqing Li, *Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers*, 70 ANTITRUST L.J. 3, 800-801 (2003).

<sup>9</sup> *Id.* at 806.

<sup>10</sup> Lars Noah, *Adding Insult to Injury: Paying For Harms Caused by a Competitor's Copycat Product*, 45 TORT TRIAL AND INSURANCE PRACTICE L.J. 3/4, 683-684 (2010).

<sup>11</sup> Legal Information Institute, *Antitrust: An Overview*, CORNELL UNIVERSITY LAW SCHOOL, <https://www.law.cornell.edu/wex/antitrust>.

<sup>12</sup> The Sherman Antitrust Act, 15 U.S.C.A. § 1.

the alleged conduct, and a *rule of reason* breach,<sup>13</sup> which requires a thorough inquiry into all the relevant circumstances to establish an anti-competitive conduct.

Until 2013, the U.S. witnessed a sharp split amongst its Circuit Courts with respect to the legality of reverse payment agreements and the kind of inquiry to be made into such agreements.<sup>14</sup> While some propagated the *illegal per se* test,<sup>15</sup> holding such agreements to be *prima facie* illegal without requiring any further inquiry, others advocated the ‘*scope of the patent*’ test,<sup>16</sup> observing that as long as the settlement was made within the scope of the patent, such reverse payment agreements were lawful, provided that the patent was not obtained by fraud.<sup>17</sup> Adding to this, the 3<sup>rd</sup> Circuit Court applied the ‘*quick look rule of reason*’ test which resembled a rule of reason analysis but required a less detailed inquiry.<sup>18</sup>

*i. The Case of FTC v. Actavis Inc.<sup>19</sup>: Emergence of the Principle of Rule of Reason*

In 2013, the Supreme Court of the U.S. (“**Supreme Court**”) settled the position by holding that reverse payment agreements were subject to the traditional *rule of reason* analysis and the fact that such settlements were entered into during the term of the patent was irrelevant, as the unexplained large payment itself reflected the patentee’s doubt regarding the weakness of its patent.<sup>20</sup> The case of *FTC v. Actavis Inc.*<sup>21</sup> (“**Actavis**”) involved Solvay’s *AndroGel* (brand drug) and related Paragraph IV Certification litigation with three generic companies including Actavis. The terms of the settlement included Solvay’s paying approximately 100 million USD to the three generics for nine years, an undertaking by Actavis that it would not enter the market until 2015, which was 65 months prior to Solvay’s patent expiry unless someone else marketed a generic before that, and the promotion of *Andro Gel* to urologists by Actavis.<sup>22</sup>

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<sup>13</sup> *Standard Oil Co. of New Jersey v. United States*, 221 U.S. 1 (1911).

<sup>14</sup> Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUMBIA L. REV. 6, 1481-1482 (2008).

<sup>15</sup> *In Re Cardizem*, 105 F. Supp. 2d 682, 705 (2000).

<sup>16</sup> *In Re Ciprofloxacin Hydrochloride* 363 F. Supp. 2d 514 (2005).

<sup>17</sup> *Flex-Foot, Inc. v. CRP Inc.*, 238 F.3d 1362, 1368 (Fed. Cir. 2001).

<sup>18</sup> *In Re K-Dur Antitrust Litigation*, 686 F.3d 197, 218 (3d Cir. 2012).

<sup>19</sup> *FTC v. Actavis, Inc.*, 570 U.S. 756 (2013).

<sup>20</sup> *Id.* at 18.

<sup>21</sup> *Id.*

<sup>22</sup> *Id.* at 5,6.

Observing the repercussions of the delayed market entry of generics and how it significantly contributed to increasing the cost of health care for the consumers, the Supreme Court reasoned on five important considerations which are as follows:<sup>23</sup>

1. *First*, since reverse payments were actually a purchase by the patentee of its already existing exclusive rights, a monopoly which could be lost if the patent was declared invalid or not infringed by the generic, such payments adversely affected the market and would be subject to antitrust scrutiny.<sup>24</sup>
2. *Second*, the anticompetitive consequences of reverse payments were capable of justification if the defendant could provide legitimate explanations for the challenged payment such as fair value for services offered by the generic drug company or saved litigation expenses.<sup>25</sup>
3. *Third*, whenever a reverse payment caused unreasonable anticompetitive damage, it could be inferred that the patentee possessed a dominant market power and was capable of maximizing its profits from the reverse payment than from facing actual competition in the market.<sup>26</sup>
4. *Fourth*, the size of the payment, its scale in relation to the payer's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of other convincing justifications were the crucial factors which required assessment to ascertain antitrust liability.<sup>27</sup>
5. *Fifth*, the litigating parties were free to enter into settlements but without any unjustified reverse payment.<sup>28</sup>

***ii. Developments Post Actavis***

Although *Actavis* settled on the rule of reason analysis and an overall reduction in the number of pay for delay agreements after the ruling,<sup>29</sup> it left the lower courts in unsettled waters by failing to lay

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<sup>23</sup> Joshua D. Wright, Commissioner, Federal Trade Commission, *Remarks at the Antitrust Master Course VII*, (Oct. 10, 2014), [https://www.ftc.gov/system/files/documents/public\\_statements/591131/141010actavisspeech.pdf](https://www.ftc.gov/system/files/documents/public_statements/591131/141010actavisspeech.pdf).

<sup>24</sup> *Actavis*, *supra* note 19 at 2234.

<sup>25</sup> *Id.* at 17.

<sup>26</sup> *Id.* at 19.

<sup>27</sup> *Id.* at 18.

<sup>28</sup> *Id.* at 19.

<sup>29</sup> Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, 1 (2014), <https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/160113mmafy14rpt.pdf>.

down a detailed and structured standard of review to assess the legality of reverse payments.<sup>30</sup> Thus, in an attempt to address the divergent views of the courts that existed earlier, *Actavis* inadvertently brought these courts back to square one by leaving unanswered questions in respect of two critical issues: *First*, what exactly constitutes ‘payments’ under *Actavis* and whether reverse payments encompass non-monetary consideration, and *second*, whether any payment over and above the estimated litigation cost threshold would amount to ‘large and unjustified’ payment, thereby attracting antitrust liability.<sup>31</sup>

Addressing the first issue as to what constitutes ‘payments’ under *Actavis*, the courts have been struggling with multi-faceted and complex settlement terms to give shape to the wide contours of the *Actavis* ruling.<sup>32</sup> An overview of the settlement agreements filed with the FTC in 2014 shows that out of the 21 potential pay for delay agreements, 6 of them had compensation styled in non-cash form.<sup>33</sup> Ranging from the legality of ‘no-Authorized Generic (“AG”) clauses<sup>34</sup> according to which the innovator agrees to not launch its AG until a fixed date, thereby amounting to ‘payment’, to intricately designed ‘acceleration clauses<sup>35</sup> which allow market entry to a generic if other generic drug companies launch their drugs before a compromise date, the District and Circuit Courts in the U.S. have been steering in the post-*Actavis* sea without any certainty.<sup>36</sup>

Although the 1<sup>st</sup> and 3<sup>rd</sup> Circuit Courts have cleared some haze by ruling that *Actavis* extends to non-monetary payments<sup>37</sup> including settlement terms such as no-AG clauses,<sup>38</sup> the post-*Actavis* environment in the U.S. is still fraught with the absence of a uniform standard of review to adjudge the anticompetitive nature of reverse payment agreements.<sup>39</sup> The authors are of the opinion that as more and more number of settlements are challenged, the courts, in the absence of a uniform standard should adopt the ‘*substance over form*’ approach and give a broader interpretation to ‘payments’ when applying the *rule of reason* analysis to the settlement terms of a case. That is, instead

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<sup>30</sup> Lauren E. Battaglia, *Defining “Payments”: The First Post-Actavis Battleground in Pharmaceutical Reverse Payments*, 2 COMPETITION POLICY INTERNATIONAL ANTITRUST CHRONICLE, 2 (2014).

<sup>31</sup> Wright, *supra* note 23, at 2.

<sup>32</sup> In Re Nexium (Esomeprazole) Antitrust Litigation, No. 12-md-2409 (D. Mass. July 30, 2015).

<sup>33</sup> Bureau of Competition, *supra* note 29.

<sup>34</sup> In re Effexor XR Antitrust Litigation, No. 3:11-cv-05479, 35 (D.N.J. Oct. 6, 2014).

<sup>35</sup> Antitrust Litigation, *supra* note 32.

<sup>36</sup> Brian Sodikoff, Thomas J. Maas and Patrick Abbott, *Reverse Payments After Actavis: Fifteen Cases to Follow*, 12 PHARMACEUTICAL LAW AND INDUSTRY REP., 999 (2014).

<sup>37</sup> In Re Lamictal Antitrust Litigation, No. 14-1243 (3d Cir. June 26, 2015).

<sup>38</sup> In Re Lipitor Antitrust Litigation, No. 14-4202, 2 (3d Cir. July 8, 2015).

<sup>39</sup> Battaglia, *supra* note 30, at 2.



of relying on the ‘form’ of payment, focus must be given to whether, after ascertainment of all the pro-competitive and anti-competitive factors, any of such forms is unexplained and unjustified. Given the complexity with which such settlements are styled, it goes without saying that the ‘type of payment’ should have no bearing on the adverse anticompetitive effects which may directly flow from such non-cash settlements.

Similarly, in addressing the second issue, the authors opine that an estimated litigation cost benchmark will only narrow down the depth of an analysis that the *rule of reason* test envisages. Therefore, instead of assessing ‘large and unjustified payments’ from an estimated litigation threshold,<sup>40</sup> the Courts should adopt a comprehensive *rule of reason* analysis which weighs out all the anticompetitive and pro-competitive effects of a reverse payment agreement.

### ***III. POSITION IN THE E.U.***

Historically speaking, the member states of the E.U. have always played a very proactive role in the regulation of the pharmaceutical industry, given that the development of this sector is quintessential for economic growth and development. The regulation of this industry is also fundamental to the policy objective of protection and promotion of health care, the importance given to which is reflected in their ever increasing budgetary expenditure, year on year, to provide access to their consumers to innovative, safe and affordable medication. Needless to say, the European Commission (“E.C.”)’s toughest fight is to create an environment which is conducive to an increasing entry of competitors into the market without compromising on the quality and affordability of services to its consumers.

The E.C. was faced with several hurdles when it observed that there was a sharp increase in State expenditure towards pharmaceuticals with disproportionate benefits to consumers. It observed that this resulted from a massive delay in the entry of generic drug companies into the market, leading to exorbitant prices of such drugs. To probe into the reasons as to why there was a market restriction of this nature, the E.C. launched a sectoral inquiry in 2008, the findings of which are discussed under Part A followed by the its judicial approach to tackling the said findings under Part B below.

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<sup>40</sup> Wright, *supra* note 23 at 12.



**A. PHARMACEUTICAL SECTOR INQUIRY: FOCUS AND FINDINGS**

The E.C.'s pharmaceutical sector inquiry was initiated on January 15, 2008. Its purpose was to investigate into the reasons for the delay of generic companies into the market for prescription drugs meant for human consumption, between 2000 and 2007, and the geographic scope of this inquiry was limited to the then existing 27 member states of the E.U.<sup>41</sup>

**i. Reasons for Generic Delay**

Statistically, it has been reported that there could have been an approximate saving of 14 Billion Euros in a situation wherein generic entry is delayed only by 7 months from the date of expiry of the originator's patent exclusivity and a potential saving of an additional 3 Billion Euros if generic entry were immediate.<sup>42</sup> These figures triggered an inquiry into the plausible reasons for such delay. Through this inquiry, the E.C. established that the delay in entry was broadly due to the uncertainty present in the market which could be attributed to the following two reasons:

1. **Conduct of Originator Companies:** It was observed that originator companies often resorted to practices that would extend the exclusivity period of the patents that they held. This could be in the form of filing numerous patent applications for the same drug (known as *patent clusters* or *patent thickets*), creating an uncertainty for generic companies as to the exact period of patent exclusivity held by the originator companies, thereby affecting their market entry.<sup>43</sup>

It was found that originator companies also resorted to the filing of divisional patent applications to extend the life of their patents. While this is a legitimate practice permitted by patent laws across the globe, it has the effect of creating the same uncertainty as to the patent exclusivity period because practically speaking, the examination of the said patent applications by the European Patent Office ("EPO") is a time-consuming procedure, consequently affecting the approximate period of exclusivity.<sup>44</sup>

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<sup>41</sup> *Final Report, Pharmaceutical Sector Inquiry*, THE EUROPEAN COMMISSION (July 8, 2009), [ec.europa.eu/.../sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](http://ec.europa.eu/.../sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf).

<sup>42</sup> Dominik Schnichels and Philipp Gasparon, Pharma Task Force, *Pharmaceutical Sector Inquiry: Presentation of the Preliminary Report*, THE EUROPEAN COMMISSION (Nov. 28, 2008), <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/si.pdf>.

<sup>43</sup> *Executive Summary of the Pharmaceutical Sector Inquiry Report*, THE EUROPEAN COMMISSION, [ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf).

<sup>44</sup> Commission Communication, *Executive Summary of the Pharmaceutical Sector Inquiry Report* (July 8, 2009), [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf); *Commission Staff Working*

2. ***Possibility of Litigation:*** The E.C. in its inquiry also observed that originator companies tend to file patent infringement suits against the incoming generics, and even the possibility of the same deters generics from actually entering the market due to the heavy time and monetary expenditure required to pursue such litigation.<sup>45</sup>

That the average time that a case takes to reach its final outcome is approximately 2.8 years, has been the biggest driving factor behind the entering into of settlement agreements between the originator and generic companies.<sup>46</sup> Neither party would want to run the risk of investing such time and money into litigation when neither of them is sure as to which way the decision of the court would swing.

Further, interim injunctions, since they are within the discretionary power of the court, are not granted in all cases. Absent a settlement agreement, if an interim order restraining generic entry is not passed, the originator would suffer huge losses as it would be required to considerably lower down its prices to compete against the generics in the market. In such a situation, even if the case is eventually decided in the originator's favor, it has already suffered financial loss that it might not be able to recover in future.<sup>47</sup> Similarly, generic companies, which are significantly smaller companies in terms of their net worth, would not be able to withstand the penalty imposed in case the court finds that it is liable for patent infringement. This anticipation causes the two parties to enter into a settlement agreement to create a win-win situation for both.<sup>48</sup>

While settlements are often encouraged by courts, the E.C. took note that some of these agreements appeared to have severely anticompetitive effects on the market. It was such settlement agreements that the E.C. went on to further probe into.

***ii. Categories of Settlement Agreements: Effect on Market Competition***

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*Document, Technical Annex to the Commission Communication Part 1*, THE EUROPEAN COMMISSION (July 8, 2009), [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf).

<sup>45</sup> Pharmaceutical Sector Inquiry, *supra* note 41.

<sup>46</sup> Pharma Task Force, *supra* note 42.

<sup>47</sup> Lukas Simas, *U.S. v. E.U.: Pay for Delay Settlements*, BERKELEY TECHNOLOGY L.J., (Nov. 12, 2015), <http://btjl.org/2015/11/us-v-eu-pay-for-delay-settlements>.

<sup>48</sup> Damien Geradin, Douglas H. Ginsburg, Graham Safty, *Reverse Payment Patent Settlements in the European Union and the United States*, GEORGE MASON UNIVERSITY LEGAL STUDIES RESEARCH PAPER SERIES, (2015), [http://www.law.gmu.edu/assets/files/publications/working\\_papers/LS1522.pdf](http://www.law.gmu.edu/assets/files/publications/working_papers/LS1522.pdf).

For the purpose of analyzing the impact of an agreement, the E.C., in its inquiry, divided all settlement agreements into two broad categories:

**Category A: No limitation on generic entry** – This envisages agreements wherein both parties agree to withdraw their claim and counter-claim respectively and there is no restriction on the entry and exit of the generic company. Since such agreements do not have anticompetitive effects on the market, the E.C. has not conducted further inquiry.

**Category B: Limitation on generic entry** – These agreements impose restrictions on the generics from marketing their own products, either wholly or partly. Such agreements are further classified into:

- **Category B. I.: Limiting generic entry without presence of value transfer** – Agreements of this nature have a high chance of being subjected to antitrust scrutiny. These agreements envisage clauses that stipulate that the generic company recognizes the validity of the originator's patent and will therefore not enter the market until expiry.<sup>49</sup> In some cases, agreements may also contain a non-challenge clause which prohibits the generic from challenging the validity of the patent in court. Such a clause, under certain circumstances, transcends beyond the specific subject-matter of the patent right and therefore, its subsequent effect of restraining competition will immediately infringe Article 101 (1) of The Functioning of the European Union (“TFEU”).<sup>50</sup>

Agreements entered into by the originator with the generic company are not by themselves invalid, so long as they are in pursuance of the *normal exercise* of its IPR, which would include all such clauses which are necessary to realize the essential function for which the right has been conferred.<sup>51</sup> The moment the agreement confers upon the originator, a right in excess of that given to it by virtue of its holding the

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<sup>49</sup> Geradin, *supra* note 48.

<sup>50</sup> Communication from the Commission, *Guidelines on the Application of Article 101 of the Treaty on the Functioning of the European Union to Technology Transfer Agreements*, OFFICIAL JOURNAL OF THE EUROPEAN UNION, (Mar. 28, 2014), [http://eur-lex.europa.eu/legal-content/en/TXT/PDF/?uri=CELEX:52014XC0328\(01\)&rid=2](http://eur-lex.europa.eu/legal-content/en/TXT/PDF/?uri=CELEX:52014XC0328(01)&rid=2).

<sup>51</sup> *Sirena SRL v. EDA SRL and Others*, C-40/70 (1971).

patent, thereby imposing additional restrictive effects on competition to that already inherent to the IPR, such an agreement is automatically subject to antitrust scrutiny.<sup>52</sup>

The idea here is that the settlement agreement should be for the pursuance of the existing right and should not be the means of creating a non-existing right.

- **Category B.II. : Limiting generic entry through value transfer** – Agreements involving a value transfer are considered to be the most dangerous form of agreements, insofar as the health of the market's competition is concerned.<sup>53</sup> It is this category of settlement agreements that the E.C. laid its primary focus on, in this inquiry.

This type of agreement may either involve a direct monetary transfer from the originator to the generic company or may involve the purchase of an asset. Either way, this consideration flows with the object of restricting the generic's entry into the market. The E.C. took cognizance of all such reverse payments that potentially threatened market competition, the outcome of which is discussed in the subsequent section.

### ***B. LEGALITY OF REVERSE PAYMENTS: THE E.U. WAY***

At the conclusion of its sectoral inquiry, the E.C. investigated into three instances of reverse payment settlement agreements – namely, the cases of *Lundbeck v. Commission*<sup>54</sup>, *Johnson & Johnson and Novartis*<sup>55</sup> and the case of *Servier-Perindopril*<sup>56</sup>. Despite there being a tried-and-tested *rule of reason* principle established by the FTC in the U.S., the E.C. interestingly took a very contrasting approach in resolving the cases before it.

This section first seeks to explain the theoretical concept of the *Per Se* or *By Object* reasoning that the E.C. resorted to in resolving the first ever case of reverse payments before it, which has only recently been affirmed by the General Court of Appeal. Subsequently, a detailed analysis of the three important cases is made.

#### ***i. 'Per Se' or 'By Object': The Concept***

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<sup>52</sup> Claudia Desogus, *Competition and Innovation in the EU Regulation of Pharmaceuticals*, 34 EUROPEAN JOURNAL OF LAW AND ECONOMICS 2, 94 (2012).

<sup>53</sup> Geradin, *supra* note 48.

<sup>54</sup> *Lundbeck v. Commission*, Case T-472/13 (2016).

<sup>55</sup> *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer*, 129 F. Supp. 2d 351 (2000).

<sup>56</sup> *Perindopril (Servier)*, COMP/AT.39612 (July 9, 2014).

According to Article 101 (1)<sup>57</sup> of the TFEU, all agreements that disrupt free competition in the European Economic Area (“EEA”)’s internal market either *by object* or *by effect* are prohibited, the two of which are alternative requirements and are to be read disjunctively.<sup>58</sup>

Restrictions *by object* are those that have such a high potential of causing a negative effect on market-competition that it is unnecessary to demonstrate any actual effects of such anti-competitiveness for such restrictions to be brought within the ambit of Article 101(1).<sup>59</sup> This presumption is based on the serious nature of the restriction, in that they are highly likely to produce such anticompetitive effects on the market and jeopardize community competition rules.<sup>60</sup> However, for a restriction to be considered anticompetitive *by effect*, the E.C. is required to actually establish the anti-competitive effect of such an agreement, taking into consideration the factual as well as legal circumstances of the case it seeks to prove.<sup>61</sup>

*ii. The Case of Lundbeck<sup>62</sup>: Findings of the Commission, Reaffirmation by the General Court and Analysis*

*Lundbeck* was the manufacturer of the anti-depressant Citalopram and held a product as well as a process patent in relation to the molecule. As the expiry of its patent exclusivity period was fast approaching, six other manufacturers were preparing to enter the market and launch their own generic versions of the drug. *Lundbeck* initiated patent infringement suits against each of the generics alleging that they would infringe the patents held by it. However, without actually pursuing the litigation, *Lundbeck* entered into settlements with them.

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<sup>57</sup> Article 101(1), TFEU: The following shall be prohibited as incompatible with the internal market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market, and in particular those which:

(a) directly or indirectly fix purchase or selling prices or any other trading conditions;

(b) limit or control production, markets, technical development, or investment;

(c) share markets or sources of supply;

(d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;

(e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

<sup>58</sup> *Société Technique Minière v. Maschinenbau Ulm GmbH*, Case 56/65, ECR 337, 249 (1966).

<sup>59</sup> Mark van der Woude, *Patent Settlements and Reverse Payments Under EU Law*, 5 COMPETITION POLICY INTERNATIONAL, 182 (2009).

<sup>60</sup> *Competition Authority v. Beef Industry Development Society Ltd.*, Case 209/07, ECR I-8637, 17 (2008).

<sup>61</sup> RICHARD WHISH & DAVID BAILEY, *COMPETITION LAW* 120 (7th ed. 2012).

<sup>62</sup> *Supra*, note 54.

The E.C. established a three-prong test, upon the fulfillment of which such agreements would be considered to be anticompetitive *by object* under Article 101 (1) of the TFEU<sup>63</sup>:

1. The originator and the generics are at least *potential* competitors when the agreements are concluded;
2. The generics commit themselves to limit, for the duration of the agreement, their independent efforts to enter one or several markets with their generic products; and
3. The agreement provided for a transfer of value from the originator, which substantially reduces the incentives of the generics to independently pursue their efforts to enter the market;

The E.C. established that the settlement agreements between the parties were well within the ambit of the test and consequently slapped the parties with a hefty fine. The parties then appealed to the General Court (“**G.C.**”), which reaffirmed the findings of the E.C. in its final decision, in the following manner:

1. As regards the *first* limb of the test, the parties argued that since *Lundbeck* held two valid patents, the question of their being considered potential competitors does not arise as the nature of the patent right automatically excludes competitors from the market.<sup>64</sup>

The E.C. relied upon some internal documents to establish that the exclusivity period of the product patent had expired before the parties entered into the settlement and therefore, the exclusionary right being contended by the parties would not hold water. Further, the E.C. also identified eight possible routes to entry into the market without infringing *Lundbeck’s* process patent and one of them, is litigation itself.<sup>65</sup> The exclusionary nature of an IPR does not go so far as to ‘exclude’ another from the market, but only to ‘try and exclude’ by pursuing litigation.<sup>66</sup> The fact that the parties did not take to litigation at all was reflective of *Lundbeck’s* knowledge that its patent was weak and that the parties in fact were potential competitors for the purpose of this test.

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<sup>63</sup> Pharma Task Force, *supra* note 42.

<sup>64</sup> Andrea Zulliet al., *The Commission’s Lundbeck Decision: A Compass to Navigate Between Scylla and Charybdis?*, (2015), [https://www.cov.com/~media/files/corporate/publications/2015/03/Lundbeck\\_decision\\_030215.pdf](https://www.cov.com/~media/files/corporate/publications/2015/03/Lundbeck_decision_030215.pdf).

<sup>65</sup> David Gregory and Imogen Proud, *First Pharma Pay-for-Delay Cases: General Court Upholds the Commission’s Lundbeck Decision*, <http://1exagu1grkmq3k572418odoooy-m-wpengine.netdna-ssl.com/wp-content/uploads/2016/09/DG-IP-Pay-for-Delay-Case-Note.pdf>.

<sup>66</sup> Mark A. Lemley, Carl Shapiro, *Probabilistic Patents*, Stanford Law School John M. Olin Program in Law and Economics Working Paper 288 (Aug. 2004), [https://www.researchgate.net/publication/4902244\\_Probabilistic\\_Patents](https://www.researchgate.net/publication/4902244_Probabilistic_Patents).

While the E.C.'s decision in this regard is mostly well-founded, what is absurd is that the E.C. finds that even in a situation wherein the generic is blocked by the patent, the parties would be considered to be potential competitors if the generics could enter the market by working around the patent.<sup>67</sup> However, it would be pertinent to mention here that the G.C., in the case of *Visa Europe Ltd. and Visa International Service v. E.C.*<sup>68</sup>, held that, in order for two parties to be considered potential competitors of one another, there must be a *real and concrete* possibility of entry into the market in the *near, foreseeable* future.<sup>69</sup> This means that so long as a party is a patent holder, establishing that another is a potential competitor would ideally not be a child's play, since the standard laid down by the G.C. is quite a strict one. Nonetheless, the E.C. seems to have made a departure from an established understanding. Secondly, the E.C. seems to have ignored that in majority of the cases the parties do not resort to litigation due to the fact that it is very time-consuming, expensive and in most cases, too uncertain for the parties to be willing to run the risk. So the parties' reluctance to engage in litigation should not be construed for their being potential competitors.

2. As far as the *second* limb is concerned, the G.C. affirmed the E.C.'s opinion in that the generics went far beyond the possible outcome of litigation by committing themselves to complete restriction from the market.<sup>70</sup> Absent the settlement, the litigation would have at best resulted in prohibiting the generics from utilizing the process over which the patent is held, but would not have restricted the generics from entering the market, in order to maintain market competition.

What the E.C. has not left room for is that in cases where parties do enter into settlements to avoid engaging in litigation, it is a normal occurrence that generics are willing to keep out of the market for a specified period if compensated for the same, when it is anticipated that their entry would result in patent infringement. This is not to say that the E.C. has erred in its decision *per se* in this case, but that this limb of the test should be considered in such a restrictive context.

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<sup>67</sup> Beef Industry, *supra* note 60.

<sup>68</sup> *Visa Europe Ltd. and Visa International Service v. E.C.*, T-461/07.

<sup>69</sup> Eduardo MartínezRivero and Guillaume Schwall, *Commission fines Visa International and Visa Europe for not admitting Morgan Stanley Bank as a Member*, Competition Policy Newsletter 1, (2008), [ec.europa.eu/competition/publications/cpn/2008\\_1\\_41.pdf](http://ec.europa.eu/competition/publications/cpn/2008_1_41.pdf).

<sup>70</sup> Enrico Di Tomaso, *Reverse Payment Settlements Under Competition Law*, THESIS, TILBURG UNIVERSITY, (2013-2014), [arno.uvt.nl/show.cgi?fid=134125](http://arno.uvt.nl/show.cgi?fid=134125).



3. As regards the *third* limb of the test, the G.C. reaffirmed that the value of consideration flowing from *Lundbeck* was a sum that roughly corresponded to the profit that the generics expected to make through successful entry into the market, in addition to which *Lundbeck* also purchased their stock, with the intention to destroy it.<sup>71</sup>

What the E.C. has blatantly ignored here is perhaps defining the threshold of value transfer beyond which a settlement agreement would be categorized as anticompetitive. A monetary transfer is a form of consideration and is usually the most demanded consideration in a settlement and therefore the fact that there is a flow of money *per se* cannot signify anti-competitiveness.<sup>72</sup> Further, what the E.C. also seems to conveniently ignore is that these are not ordinary settlements but are *patent* settlements – predicated upon an intellectual property right that confers a certain kind of exclusivity. Due to this, the value of settlement is usually significantly higher as compared to ordinary settlements.<sup>73</sup>

While the three-prong test may have its fair share of loopholes, it would be incorrect to say that this test cannot be successfully applied at all. What should not be done, however, is to consider this test as a conclusive mechanism to establish anti-competitiveness, as the E.C. and G.C. have done. The real issue here is not the test, but the approach that has been taken on the basis of this test, that is, declaring the agreements anti-competitive *by object*.

While the E.C. in its sector inquiry report categorically stated that “*any assessment of whether a certain settlement could be deemed compatible or incompatible with the E.C. competition law would require a full blown analysis of the individual agreement, by taking into account the factual, economic and legal background of each case*”<sup>74</sup>, it has nonetheless ignored its own suggestion.

Further, the E.C.’s task of defending its reasoning for resorting to the *by object* approach will undoubtedly be very difficult, in light of the European Court of Justice’s judgment in the *Cartes Bancaires* case wherein it held that “*only conduct whose harmful nature is proven and easily identifiable, in light of experience and economics, should therefore be regarded as a restriction of competition by object, and not agreements*

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<sup>71</sup> Sven Gallasch, *European Pharmaceutical Antitrust after Groupment des Cartes Bancaires – Time to Rethink the Approach to Pay For Delay Settlements?*, COMPETITION POLICY BLOG, UNIVERSITY OF EAST ANGLIA, <https://competitionpolicy.wordpress.com/2014/10/20/european-pharmaceutical-antitrust-after-groupment-des-cartes-bancaires-time-to-rethink-the-approach-to-pay-for-delay-settlements/>.

<sup>72</sup> Whish, *supra* note 61.

<sup>73</sup> James Killick, Jérémie Jourdan and Jerome Dickinson, *The Commission’s Lundbeck Decision: A Critical Review of the Commission’s Test for Patent Settlement Agreements*, COMPETITION POLICY INTERNATIONAL, (Feb. 24, 2015).

<sup>74</sup> Pharmaceutical Sector Inquiry, *supra* note 42, at 1530.

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*which, having regard to their context, have ambivalent effects on the market or which produce ancillary restrictive effects necessary for the pursuit of a main object which does not restrict competition”<sup>75</sup>*

This leads us to question the E.C.’s decision as to whether the same was driven by strategic reasons<sup>76</sup> – in that it is much easier to close a case when no such ‘full blown’ analysis is required to be made, or no anticompetitive effects of the agreements in question have to be established.

**iii. Other instances of Reverse Payments**

There have been two other prominent cases of reverse payments before the E.C. – the first of them being the case of *Johnson & Johnson and Novartis*<sup>77</sup> wherein the E.C. found that the co-promotion agreement entered into by Johnson & Johnson and Novartis, stipulating that Novartis would jointly promote Johnson & Johnson’s drug *Fenanyl*, in consideration of a monthly value transfer for the same was anticompetitive *by object* as it qualified the three limbs of the three-prong test. No appeal was filed by either party against the decision of the E.C.<sup>78</sup>

The other notable instance of reverse payments was the *Servier-Perindopril*<sup>79</sup> case which is a rather interesting one, for the fact that even though the approach ultimately followed by the E.C. was identical to the preceding cases, its approach also contains a novelty. That even though the settlement agreements were deductively a *by object* infringement of Article 101 (1) of the TFEU due to being caught by the three-prong test, the E.C. thought it necessary to specifically establish the anticompetitive effects of the settlement agreements on the market, for the “sake of completeness”.<sup>80</sup> This perhaps came in light of the sharp criticism against its un-reasoned *by object* approach taken in its previous two cases. While this third case was also ultimately decided in the same manner as its predecessors, is this reflective of a plausible convergence of the E.U.’s approach with the U.S.’s *rule of reason*?

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<sup>75</sup> *Groupement Des Cartes Bancaires v. European Commission*, Case 67/13 P (2014).

<sup>76</sup> Sven Gallasch, *Activating Actavis in Europe – The Proposal of a “Structured Effects Based” Analysis for Pay for Delay Settlements*, UNIVERSITY OF EAST ANGLIA LAW SCHOOL, CENTRE FOR COMPETITION POLICY WORKING PAPER 15-3,(2016),<http://competitionpolicy.ac.uk/documents/8158338/8368036/CCP+Working+Paper+15-3.pdf/8226205f-c0e2-4157-aed5-87dbfbebacc>.

<sup>77</sup> *Novartis*, *supra* note 55.

<sup>78</sup> Christos Malamataris, *Johnson & Johnson / Novartis: Another Pay-For-Delay Down for the European Commission*, INSIDE EU LIFE SCIENCES, (Dec. 13, 2013), <https://www.insideeulifesciences.com/2013/12/13/johnson-johnson-novartis-another-pay-for-delay-down-for-the-european-commission/>.

<sup>79</sup> *Servier*, *supra* note 56.

<sup>80</sup> Miranda Coleet al., *European Commission Published Non-Confidential Version of Servier Decision*, INSIDE EU LIFE SCIENCES, (July 17, 2015), <https://www.insideeulifesciences.com/2015/07/17/european-commission-published-non-confidential-version-of-servier-decision/>.

***IV. COMPARISON BETWEEN U.S. AND E.U.***

In this section, the authors seek to draw a comparison between the contrasting approaches taken by the U.S. and E.U. in tackling the instances of reverse payment patent settlement agreements that arose in their respective jurisdictions. While the principle developed by the FTC is a settled one, the approach resorted to by the E.C. has drawn flak from critics all over the world for reasons delineated below. The ultimate question left to be answered now is, is it more desirable that the E.U. soften its stand and employ a well-reasoned approach like the U.S.?

***A. POSITION IN THE U.S.***

While exploring the legality of reverse payment agreements in the hands of the U.S. Judiciary, it was observed and explained in Part II of the paper that the Supreme Court of the U.S. in *Actavis* upheld the *rule of reason* analysis over the *illegal per se* test. Thus, ascertainment of the anticompetitive nature of reverse payment agreements requires a comprehensive analysis of all the relevant factors on a case by case basis, as the terms of the settlement are multi-faceted.

In addition, we also observed that the regulatory framework under the Hatch Waxman Act is such that it allows the generics to enter the market before the expiry of the patent exclusivity period. However, such generic company would be required to file an ANDA as well as a Paragraph IV Certification with the FDA, mentioning every related patent filed by the originator company in the market it seeks to enter.<sup>81</sup> The FDA would only approve the generic's application if it finds that its entry will not infringe the originator's patent rights and this is called a *patent linkage*.<sup>82</sup> The idea here is to ensure that only such originator companies that still hold valid patents should be allowed to enjoy the monopolistic benefits that flow from an IP. However, the originator company still has the opportunity to file a patent infringement suit against such generic.

Further, the Hatch Waxman Act essentially seeks to incentivize generics to enter the market by allowing the first filer a 180-day exclusivity period during which no one generic company will be allowed to enter and market its own version of the drug.<sup>83</sup> The consequence of this is that the originator company has the power to foreclose the entire market by entering into a settlement with the first filer generic company. What the U.S. lawmakers perhaps overlooked is that this 180-day

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<sup>81</sup> Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355 (j)(2)(A)(vii) (2010).

<sup>82</sup> Gallasch, *supra* note 76.

<sup>83</sup> *Id.* at § 355 (j)(5)(B)(iv).

period would continue to subsist even in a situation where the two companies enter into such reverse payment settlement agreements.

Nonetheless, when the *Actavis*-advocated rule of reason analysis is placed in this regulatory context, it flows that despite the high possibility of an anticompetitive effect resulting from a settlement agreement of such nature, a full blown analysis of the cumulative pro-competitive and anticompetitive effects of the same will have to be demonstrated to determine the legality of such payments. This is because the FTC recognizes that such agreements are not just ordinary settlements but involve patents as its subject matter and therefore the terms of settlement, although may appear to be anticompetitive, may not actually have such a negative effect on competition in the market.<sup>84</sup>

***B. POSITION IN THE E.U.***

The E.U. lacks a regulatory framework on the lines of the Hatch Waxman Act, with particular reference to the first-filer advantage given to generic companies. Additionally, the E.U. also does not recognize the concept of *patent linkage*.<sup>85</sup> In other words, when the European drug safety regulators approve the entry of drug companies into the market, the only consideration on which such approval is granted is the quality, safety and efficacy of the drug, and factors such as economic and other considerations, including the existence of patent holders in the market are immaterial. Therefore, the regulator is not limited in the number of generic drug applications it can approve, so long as they are compliant with the necessary health and safety standards.<sup>86</sup>

As a consequence, the originator company does not have the same power of foreclosure as it would have had in the U.S. For the originator to actually foreclose the market, it would have to enter into separate settlements with each of the generics entering the market. Therefore, it is clear that even if the originator company entered into a settlement agreement with one generic company, it would not necessarily have an anticompetitive effect on the market, the likelihood of which is much higher in the U.S.

If we were to now read the E.U.'s approach of categorizing reverse payment settlement agreements in this background of an absence of such regulatory framework, it appears that the approach resorted to by the E.U. is extremely harsh. The E.C. in its decisions seems to have overlooked that

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<sup>84</sup>Actavis, *supra* note 19.

<sup>85</sup>Gallasch, *supra* note 76.

<sup>86</sup>*Id.*

there could be several reasons for a brand company and a generic company to enter into a settlement agreement, other than just to create entry restrictions in the market.<sup>87</sup> One such reason is essentially to avoid running the risk of the uncertain outcome of litigation coupled with the exorbitant costs and time involved. Further, owing to the fact that it is a patent settlement agreement and not just an ordinary one, a higher flow of consideration is understandable.<sup>88</sup> And therefore, to hold such agreements on account of their high value transfer as anticompetitive *per se* would not be well-founded. This could be traced down to a fundamental concept of contract law that the value of consideration is immaterial in an agreement and is valid so long as it is acceptable to both parties. Here, the E.C. also seems to have ignored the possibility that the originator companies could be compensating for several other costs in addition to the estimated legal costs, which, without the creation of an adverse effect on competition, should not be of concern to the competition authorities. Interestingly, the E.C. in its decision has not prescribed any threshold for the value of the consideration flowing in such agreements beyond which they would be considered illegal, further creating more uncertainty.<sup>89</sup>

It is argued that while the quantum of value transfer may be an *indication* of the existence of an anticompetitive agreement, it nonetheless cannot be used as *conclusive* proof. This understanding has also been reiterated by European courts time and again, particularly in the case of *Delimitis v. HenningerBrau*,<sup>90</sup> wherein the court held that agreements which appear anticompetitive are not necessarily so, as such agreements may result in significant precompetitive effects, with the anticompetitive effects being only an ancillary part of the same. However, the E.C. seems to have overlooked this understanding in its decisions.<sup>91</sup>

Having regard to the existing patent law and regulatory system along with the E.C. competition principles, we think it desirable for the E.U. to take a more analysis-based approach, taking into consideration the specific nature of patent settlement agreements. To reiterate, while the quantum of a value transfer may be a possible indication of an adverse effect on competition, the E.C. should lay

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<sup>87</sup> Anita Esslinger, *A Wolf in Sheep's Clothing – Is Your Litigation Settlement Anti-Competitive?*, EU AND COMPETITION LAW, (Dec. 17, 2014), <http://eu-competitionlaw.com/a-wolf-in-sheeps-clothing-is-your-litigation-settlement-anti-competitive/>.

<sup>88</sup> Gregory, *supra* note 65.

<sup>89</sup> Executive Summary, *supra* note 44.

<sup>90</sup> Stergios Delimitis v. Henninger Bräu AG., Case C-234/89, ECR 1991 I-00935 (1991).

<sup>91</sup> Paul Bridgeland, *Court of First Instance Upholds Three Commission Decisions Relating to Beer Ties*, COMPETITION POLICY NEWSLETTER 2, (June 2002), [http://ec.europa.eu/competition/publications/cpn/2002\\_2\\_45.pdf](http://ec.europa.eu/competition/publications/cpn/2002_2_45.pdf).

greater emphasis on the nature of the market – particularly the number and size of each player, to assess the actual impact of a settlement agreement. A well-reasoned approach of this nature could go a long way in improving the level of certainty in the E.U. market.

## V. POSITION IN INDIA

Anticompetitive scrutiny of reverse payments is still at a budding stage in India due to lack of any authoritative ruling. Therefore, this section seeks to explore the contours of the Indian pharmaceutical industry after which the authors comment on the approach likely to be adopted by the Competition Commission and the judiciary, between the two contrasting approaches followed by the U.S. and the E.U., available to them.

### A. THE INDIAN PHARMACEUTICAL INDUSTRY

Until 2005, product patents were not recognized in India thereby immensely assisting the Indian pharmaceutical companies in mastering the art of reverse engineering brand drugs innovated by foreign pharmaceutical companies.<sup>92</sup> Very soon, the Indian pharmaceutical industry, which largely comprised of generic and bulk drug manufacturers,<sup>93</sup> came to be regarded as the *pharmacy of the poor* across the globe.<sup>94</sup> However, under an obligation to align its IPR laws with the commitments made under Trade Related Intellectual Property Rights (“**TRIPS**”),<sup>95</sup> the Indian Patents Act of 1970 underwent substantial amendments in 2005,<sup>96</sup> one of which was the recognition of product patents in India for food, chemicals and pharmaceuticals.<sup>97</sup> As a result, the Indian generic manufacturers were prohibited from reverse engineering brand drugs and had to wait until the expiry of an existing patent to manufacture a generic variant of the brand drug.

Needless to say, a change in the pharmaceutical market-dynamics will necessarily ensue from a change in the position of law. Thus, with the recognition of product patents, not only will foreign innovators re-enter the Indian drug market and enjoy patent protection over their brand drugs, but

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<sup>92</sup> Dr. Muralikallumal, *Trends in India's Trade in the Pharmaceutical Sector: Some Insights*, WTO REPORT, (Aug. 2012), <http://wtocentre.iift.ac.in/workingpaper/Working%20Paper2.pdf>.

<sup>93</sup> Pandey Shivanand, *India's Pharmaceutical Industry on Course for Globalization: A Review*, 1 INTERNATIONAL JOURNAL OF PHARMACY AND LIFE SCIENCES 3, 137-138 (2010).

<sup>94</sup> Sreelekshmi Rajeswari, *India – No Longer The Pharmacy of The Developing World?*, CAMBRIDGE GLOBALIST, (Oct. 15, 2016), <http://cambridgeglobalist.org/2016/01/30/india-no-longer-the-pharmacy-of-the-developing-world/>.

<sup>95</sup> Dr. V. Manickavasagam, *Intellectual Property Rights and The Impact of Trips Agreement With Reference To Indian Patent Law*, PLANNING COMMISSION (SER DIVISION) GOVERNMENT OF INDIA, (Dec. 2007), [http://planningcommission.gov.in/reports/sereport/ser/ser\\_alla.pdf](http://planningcommission.gov.in/reports/sereport/ser/ser_alla.pdf).

<sup>96</sup> The Patents (Amendment) Act, 2005.

<sup>97</sup> *Id.* at 3.

the swift expansion of the Indian pharmaceutical industry will also see an increase in patent infringement litigation between multinational innovators and domestic generics.<sup>98</sup> Consequently, the inducement to capture the market and restrict entry of low-priced generics will only be aggravated with time, and similar to the U.S. and the E.U. markets, India may witness reverse payment agreements disguised as genuine patent infringement settlements. This is further substantiated by the fact that Indian generic manufacturers have already left a mark abroad by entering into reverse payment agreements with foreign drug innovators.<sup>99</sup>

### ***B. REGULATORY FRAMEWORK***

Till date, there has been no authoritative ruling by any Indian court on the legality of reverse payment agreements in India but in light of the recent penalties imposed on the Indian generics by the E.C. for effecting reverse payment deals,<sup>100</sup> the Competition Commission of India (“**CCI**”) has been strictly monitoring the behavioral abuse in the Indian pharmaceutical industry.<sup>101</sup> Additionally, the CCI has entered into a Memorandum of Understanding with the U.S. Department of Justice and the FTC to observe increased cooperation and exchange of information in important competition policies and enforcement developments.<sup>102</sup> This only makes it more apparent that India may trail on the footsteps of the FTC in vigorously supervising and investigating any out-of-court patent infringement settlements which have or may have an appreciable adverse effect on competition (“**AAEC**”)<sup>103</sup> in the Indian drug market.

The Indian Competition Act of 2002 (“**Competition Act**”) aims to prevent practices which have an adverse effect on competition and strives to promote and sustain competition in the markets and protect consumer interests.<sup>104</sup> In the pharmaceutical sphere, any agreement between the innovators and the generics to delay the generic drug’s market entry or to foreclose the market may come under

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<sup>98</sup> Ravinder Jha, *Options for Indian Pharmaceutical Industry in the Changing Environment*, 42 ECONOMIC AND POLITICAL WEEKLY 39 (2007).

<sup>99</sup> Lundbeck, *supra* note 54.

<sup>100</sup> Servier, *supra* note 56, at 806-809.

<sup>101</sup> Vaibhav Choukse, *Sweetheart Deals That Hurt Consumers*, BUSINESS STANDARD, September 15, 2014, [http://www.business-standard.com/article/opinion/vaibhav-choukse-sweetheart-deals-that-hurt-consumers-114091501332\\_1.html](http://www.business-standard.com/article/opinion/vaibhav-choukse-sweetheart-deals-that-hurt-consumers-114091501332_1.html).

<sup>102</sup> U.S.-India Memorandum of Understanding, (Sept. 2012), <https://www.ftc.gov/system/files/1209indiamou.pdf>.

<sup>103</sup> Section 19(3), The Competition Act, 2002.

<sup>104</sup> Preamble, The Competition Act, 2002.



the radar of Competition Act if it causes or is likely to cause an AAEC on the Indian drug market.<sup>105</sup> Particularly such agreements may be declared as anticompetitive under Section 3(1), which is the general provision prohibiting anticompetitive agreements in India and requires a *rule of reason* analysis to establish AAEC in the relevant market, or under Section 3(3), which specifically prohibits horizontal agreements between parties engaged in identical or similar trade of goods or provision of services. It codifies a *per se illegal* analysis without any further requirement to establish AAEC and therefore a reverse payment agreement which directly or indirectly determines the drug prices, or limits or controls production, supply and markets for drugs will prima facie be declared anti-competitive.

Such agreements, if they result in foreclosure of effective competition in the relevant drug market may also be investigated under Section 4 of the Competition Act which prohibits abuse of dominant position.<sup>106</sup> However, given the constant interaction of IPRs with Competition Law, the catch here is Section 3(5) of the Competition Act which gives an umbrella protection to IPRs from the rigors of antitrust scrutiny.<sup>107</sup> Statutorily, it would mean that the innovator drug company could impose reasonable conditions to restrain any infringement of its patented drug by the generics but whether or not the same can be extended to cover reverse payment agreements entered during the term of the patent is questionable. The authors are of the opinion that since it is well settled that IPRs cannot transgress antitrust scrutiny beyond the scope of exclusivity that they offer, Section 3(5) of the Competition Act can hence not be interpreted in a manner which ultimately perpetuates the ever-greening of patents. This is further substantiated by the negative impact that such reverse payments may have on patients and the healthcare sector at large and the reasoning of the U.S. Supreme Court in *Actavis*,<sup>108</sup> that a valid patent does not automatically shield a reverse payment agreement from antitrust scrutiny.

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<sup>105</sup> Dr. Geeta Gouri, *Competition Issues in the Generic Pharmaceuticals Industry in India*, [http://www.cci.gov.in/images/media/presentations/ComIssGenPharmIndusIndia\\_20100401142346.pdf](http://www.cci.gov.in/images/media/presentations/ComIssGenPharmIndusIndia_20100401142346.pdf) (last updated on October 9, 2014).

<sup>106</sup> *Competition Issues in The Pharmaceutical Industry*, INDIA COMPETITION AND REGULATION REP., 5 (2007), [http://www.cuts-international.org/pdf/ICRR07\\_%20Pharma.pdf](http://www.cuts-international.org/pdf/ICRR07_%20Pharma.pdf).

<sup>107</sup>*Id.* at 39.

<sup>108</sup>*Actavis*, *supra* note 19.

***C. POSSIBLE JUDICIAL APPROACH***

Although the legality of reverse payment agreements is still unaddressed in India, a case which did spur the need to address the issue was a Delhi High Court directed mediation<sup>109</sup> between *Hoffman-La Roche*, a Swiss innovator and *Cipla*, an Indian generic to reach a settlement over the alleged patent infringement by *Cipla* of *Roche's Tarceva* tablets, by manufacturing its generic version. Interestingly, the Court had upheld the validity of *Roche's* and *Cipla* was not found to infringe it. Although the mediation failed, if the terms of the settlement had resulted in *Cipla's* not marketing its generic drug, the CCI would have had the *suomotu* power to inspect the terms of the settlement under the above-mentioned provisions of the Competition Act. An analysis of pharmaceutical cases shows that foreign innovators majorly resort to permanent injunctions and ever greening of patents (patent clusters) to defend the exclusive sale of their brand drugs in the Indian market.<sup>110</sup>

However, as and when it comes for consideration, the authors are of the opinion that the Indian Judiciary will adopt a *rule of reason* approach similar to *Actavis*,<sup>111</sup> over the E.U.'s *per se illegal* approach in determining the anti-competitive nature of reverse payment agreements.

***VI. CONCLUSION***

Having explored the legality of reverse payment patent settlements on both sides of the Atlantic, we understand that the U.S. has taken an approach that seems to be considered as the most acceptable way to treat such agreements. The FTC has recognized the peculiar nature of patent settlements and has therefore suggested that a full-blown case by case analysis should be done. Consequently, a comparison between the cumulative pro-competitive and anticompetitive effects of an agreement on the market is required to be established to adjudge the legality of a reverse payment agreements. Further, although FTC's scrutiny of patent settlements has strengthened over the years, the current practice of large monetary remedies, spiking up to 1.2 billion dollars, may have to give way to less stringent enforcement tools resulting in use of disgorgement only in rare cases.

The E.U.'s approach, on the other hand, has drawn considerable flak from critics across the globe for being too harsh and inconsiderate. Laying most of its focus on the quantum of payment in the

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<sup>109</sup> F. Hoffmann-LA Roche Limited and Another v. Cipla Limited, 202 (2013) DLT 603.

<sup>110</sup> C.H. Unnikrishnan, *CCI to Scan Drug Patent Settlements*, LIVEMINT, August 3, 2014, <http://www.livemint.com/Companies/RVVDhRh7oTfpqIphkb6jM/CCI-to-scan-drug-patent-settlements.html>.

<sup>111</sup> *Actavis*, *supra* note 19.

settlement agreement, what is apparent is that the E.U. has most certainly overlooked the peculiar nature of patent settlements, creating an *elephant in the room* situation.

Further, given the nature of the E.U.'s regulatory framework, the possibility of a reverse payment agreement having an adverse effect on market competition is substantially lower than in its U.S. counterpart. The E.C. has taken note of the loopholes in the E.U. regulatory framework, with particular reference to the lack of a community patent resulting in exorbitant cost of patent filing and the lack of efficient procedures for faster approval of patent applications. Acknowledging that it is these shortcomings that cause parties to resort to settlement agreements of this nature, the E.C. has even suggested member states to cooperate towards overcoming these impending hurdles. However, despite this, the E.C. continues to take a strict stand on the matter.

We understand that the E.C.'s stringent approach is reflective of the ultimate importance that it gives to ensuring that it is able to provide safe, efficacious and affordable healthcare to its consumers. We also acknowledge that the same could be a consequence of the fact that historically the member states of the E.U. have played a more significant role in the protection of the health industry than the U.S. However, we feel that an approach as restrictive as that taken by the E.C. could eventually become counter-productive, as it may dis-incentivize generics from even entering the market in the first place, due to the amount of legal uncertainty that currently exists.

It is therefore suggested that the E.C. should take into consideration the nature of the market in addition to the factors it already looks into, to create a more conclusive mechanism to decide the adverse effects of a patent settlement agreement on the market. By progressing from a *by object* approach to a *by effects* approach, the E.C. could go a long way in creating that legal certainty, which would be somewhere on the lines of the *rule of reason* mechanism followed by the U.S. Since the TFEU already envisages such a mechanism, legislative interference is not even required.

So far as the question of convergence of the two approaches is concerned, it is pertinent to understand that what lies at the heart of such convergence is the ultimate policy objective of the U.S. and E.U. respectively. It appears to us that the U.S.'s policy is to try and create a perfect balance between catering to consumers but to also respect the profit-making motive of capitalistic players in the market. On the other hand, the E.U. seems to lay greater importance on the protection of its consumers in the health industry. Therefore, as much as we are hopeful that the two approaches will eventually converge, whether the same will actually happen, only time will tell.

In conclusion, from an Indian perspective, although the lack of an authoritative ruling leaves the legality of reverse payment settlements unaddressed, we strongly believe that India will most likely adopt a *rule of reason* analysis, similar to the U.S. to adjudge the anti-competitive nature of such settlements.