TRANSATLANTIC DEVELOPMENT OF ANTITRUST JURISPRUDENCE: BRIDGING THE RULE GAP IN PATENT DISPUTE SETTLEMENT REGULATION

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ABSTRACT

Patent dispute settlements have remained controversial as an anticompetitive patent practice in the pharmaceutical sector. Reverse payment settlements in particular have been on the rise on both sides of the Atlantic. They were traditionally induced in the different regulatory contexts of the United States and European Union but have since occurred without contextual divergence. Antitrust law governing reverse payment settlements has seen the vigorous development of jurisprudence by virtue of the vibrant exchange of substantive feedback between the United States and European Union. The U.S. Supreme Court’s judgment in Actavis in 2013 provided a well-marked roadmap and guiding principles for reverse payment antitrust analysis while the Court of Justice of the European Union provided further clarification and elaboration in its first full-blown analysis in Lundbeck in 2021. Joint and complementary reading of Actavis and Lundbeck, on top of other key decisions, serves, significantly, to close many jurisprudential loopholes that have been perceived to exist in either jurisdiction and thereby successfully bridges the rule gap that could have remained wide without robust transatlantic interaction. This Article purports mainly to provide an in-depth analysis of reverse payment settlements in the global context by discussing antitrust theories and practices in the United States and European Union from both comparative and reciprocal perspectives. This Article contributes substantially to the future mandate to establish the comprehensive legal framework of a higher magnitude of integrity and legitimacy in substance, which facilitates effective antitrust scrutiny for patent dispute settlement regulation. This Article reveals that the critical examination of convergence and divergence between the U.S. and EU antitrust law leads to the transatlantic development of jurisprudence as opposed to intensifying further complexity that might have occurred if the law and policy across the Atlantic had failed to share the common essence in carving out the effective rules due to the want of reciprocal and complementary approach.

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I. INTRODUCTION: CONVERGING PATHS AT A FORK IN THE ROAD

The pharmaceutical industry across the world has witnessed rapid growth in market size and technological innovation. The advance of pharmaceutical technology has not merely furthered cross-border trade on a larger scale than ever, but also altered the market structure and the competitive landscape. Deepened competition has entailed a surge of transnational anticompetitive practices by market entities. Continuous regulatory response to these practices has driven the development of jurisprudence in competition law and policy across the globe.

Current propensity in antitrust regulation of the pharmaceutical industry gives salience to reverse payment settlements, also known as pay-for-delay settlements. These settlements are a problematic class of patent settlement agreements by which firms settle disputes over patent infringement or licensing.1 In settlements, a patent infringement plaintiff pays an infringing defendant to stay out of the market for the negotiated term.2 Reverse payment settlements occur when a name-brand firm producing a patented drug pays a generic firm.3 These patent practices have the deleterious effect on consumer welfare by setting back, or delaying, earlier entry of lower-price generic drugs and reducing competition in the relevant market.4 Therefore, reverse payment settlements have come under robust antitrust scrutiny across the globe, particularly in the United States and European Union.5

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2. Id.
3. Id.
4. Id.
5. Id.
Courts on both sides of the Atlantic have increasingly witnessed pay-for-delay deals. The deals were traditionally induced in different regulatory contexts in the United States and European Union but have since occurred without contextual divergence. While the U.S. Supreme Court’s Federal Trade Commission v. Actavis, Inc. decision in 2013 on anticompetitive reverse payment settlements set a precedent in U.S. antitrust law, the Court of Justice of the European Union, which is the European Union’s highest court that possesses appellate jurisdiction, issued its landmark judgment on the legality of reverse payment settlements in Lundbeck v. European Commission in 2021. Actavis and Lundbeck are distinguished from each other in factual details and governing rules applied but follow a convergent path in analytical approach. Hence, a close look at Actavis and Lundbeck from comparative and complementary perspectives serves to fill jurisprudential loopholes in both of them.

This Article disproves that the development of antitrust law to date has seen a transatlantic divide on reverse payment settlement regulation, regulatory challenges, and practical concerns over legal expectations in transnational patent practices. Antitrust law in the United States and European Union generally takes a different modality of approach. This Article, nonetheless, holds that there is no significant degree of rule disparity between jurisdictions that could challenge and complicate harmonious rule interpretation and application. This Article, instead, finds the considerable magnitude of commonality in legal substance which reflects the potential for the creation of a new paradigm to accommodate transatlantic regulatory dynamics. This Article argues that reading Actavis and Lundbeck together through a critical lens merit more credit than merely letting those cases stand alone in jurisdictional silos. Such interactive rule interpretation serves to counterbalance any imperfection and eliminate any equivocality that may remain outstanding in either jurisdiction. Moreover, the emerging need to refine and clarify current antitrust jurisprudence vindicates the adoption of an integrated approach that explores inter-compatibility and inter-complementarity to determine how they can feed back into each other to form a comprehensive legal framework of a higher magnitude of integrity and legitimacy in substance. The rule synthesis, as formulated in a positive feedback loop, can obviate the danger of the accumulation of misleading rules by building one on top of another. A proactive

6. Id.
10. See infra Part II & III.
11. See infra Part V.
12. See infra Part V.
initiative toward integrative jurisprudence can be a legal solution to regulatory limitations stemming from a legal hiatus on account of the ineffectiveness or lack of existing rules. 13 A new legal framework, as systemically and substantively redesigned by virtue of seamless consolidation between the U.S. and EU antitrust rules, would serve to streamline a complicated reverse payment analysis and advance analysis that does not stoke further complexity. 14 This integrative framework enables courts and regulatory authorities to navigate antitrust scrutiny without any transatlantic conflicts. 15

With this recognition, this Article substantiates that the transatlantic development of jurisprudence has shaped the regulatory landscape by bridging the existing rule gap. First, Part II examines U.S. antitrust theories and practices as established by *Actavis* and subsequently developed by the robust accumulation of post-*Actavis* case law. 16 Part III discusses EU antitrust theories and practices as shaped by the European Commission’s landmark decisions in *Lundbeck* and *Perindopril (Servier)* in 2013 and 2014, respectively, as well as the first judicial judgment by the Court of Justice of the European Union in *Lundbeck*. 17 Part IV probes how *Actavis*, *Lundbeck*, and *Servier* closely inform one another to advance a coherent and consistent form of rule development. In this respect, Part IV investigates the convergence and divergence in dominant antitrust rules between the United States and European Union and identifies how they serve to fill gaps through mutual recognition and integration. 18 In essence, Part IV thoroughly compares and analyzes those rules to discover seven salient points of law on which the United States and European Union are found to stand in accordance or contrast with each other. 19 Part IV, then, synthesizes with special prudence those discovered conterminous rules and offers multifaceted legal implications creating an overarching legal framework that systemically strikes the delicate balance between the U.S. and EU antitrust law. 20 Lastly, Part V sheds light on the need to pioneer a new path on rule elaboration and clarification. 21 Part V concludes with insights into why the reciprocal and complementary approach to rule development

13. See infra Part V.
14. See infra Part V.
15. See infra Part V.
16. See infra Part II.
17. See infra Part III.
18. See infra Part IV.
19. See infra Part IV.
20. See infra Part IV.
21. See infra Part V.
advances the establishment of a harmonious, sustainable, and well-structured legal framework for reverse payment antitrust regulation.22

II. ANTITRUST THEORIES AND PRACTICES IN THE UNITED STATES

A. Legal Framework for Reverse Payment Regulation

Since reverse payment settlements emerged as reciprocal business tactics and arrangements designed for market dominance and profit-sharing between pharmaceutical patentees and unpatented rivals, these patent practices have been “on the rise on both sides of the Atlantic.”23 Reverse payment deals were traditionally induced in a different regulatory context in the United States and European Union but have since occurred without contextual divergence.24 A new drug placed in the U.S. market must undergo a new drug application process and receive subsequent Federal Drug Administration (FDA) approval. To approve a drug the FDA evaluates the safety and effectiveness of the drug.25 The Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act) amended the Federal Food, Drug, and Cosmetic Act of 1938 and set out a detailed regulatory framework that governs the new drug application process.26

It is noteworthy that the Hatch-Waxman Act sets forth the unique statutory drug approval-patent linkage scheme, which reveals a sharp contrast with the EU regulatory framework, as it does not have any equivalent.27 The Hatch-Waxman Act allows a drug applicant to request permission to sell a generic drug by filing an Abbreviated New Drug Application (ANDA).28 In the ANDA process, the applicant must certify that any patent covering the brand version of the drug has expired or, as is more relevant here, that the patent is “invalid or will not be infringed by” the sale of the generic because the invention was obvious, or the patent was procured by fraud.29 The brand may defend the validity of its patent by

22. See infra Part V.
23. Bokhari, supra note 1, at 739.
27. See Gürkaynak et al., supra note 24, at 156–57.
filing a suit against the generic within 45 days.\textsuperscript{30} The brand ordinarily does sue because the FDA must then refrain from approving the generic’s ANDA for 30 months in order to give the parties sufficient time to litigate the validity of the patent.\textsuperscript{31}

The Hatch-Waxman Act provides an additional incentive to generic manufacturers to challenge the patents they believe are invalid. The first applicant to file an ANDA with the above certification receives a 180-day period of exclusivity; during which no other manufacturer may sell a generic version of the drug.\textsuperscript{32} During those 180 days, the generic applicant need only compete with the branded drug, or with the authorized generic (AG) should the branded manufacturer decide to produce one, but not with a number of other generics that may enter the market soon after a patent expires or is invalidated.\textsuperscript{33}

Both the brand and generic firms have an important incentive to prevail in the patent infringement suit. The brand can preserve its patent monopoly by proving the patent is valid. The generic, however, if it proves the patent is invalid, can enter the market with the advantage of the 180-day exclusivity period.\textsuperscript{34} Both parties also have a compelling reason to settle the patent infringement suit, in addition to avoiding the cost of prolonged litigation. Typically, after the first-filing generic firm’s 180-day period of exclusivity ends, additional generic firms enter the market before patent expiration.\textsuperscript{35} This prospect of entry by a second (or third) generic makes it even more valuable to the branded firm to enter into a pay-for-delay settlement with the first-filing generic because drug prices, and hence the branded firm’s profits, fall further in response to subsequent generic entry than they do in response to the first generic entrant.\textsuperscript{36} With multiple generic entrants, delaying generic entry will boost profits even more—and harm competition even more—than with just one generic entrant.\textsuperscript{37} As a result, payment for delay is even more tempting for the settling parties and even more harmful to consumers.\textsuperscript{38} By

\begin{itemize}
  \item \textsuperscript{30} Id. § 355(j)(5)(B)(iii).
  \item \textsuperscript{31} See id.
  \item \textsuperscript{32} See id. § 355(j)(5)(B)(iv).
  \item \textsuperscript{33} See id.
  \item \textsuperscript{34} See id.
  \item \textsuperscript{35} Aaron Edlin et al., \textit{The Actavis Inference: Theory and Practice}, 67 RUTGERS U. L. REV. 585, 607 (2015) (“A fully litigated declaration of patent invalidity would estop the branded firm from asserting its patent against other generics, so after 180 days other generics would be able to enter the market as well.”).
  \item \textsuperscript{36} See id.
  \item \textsuperscript{37} Id.
  \item \textsuperscript{38} Id.
\end{itemize}
reaching a settlement agreement before the court might invalidate the patent, the patent continues to create a genuine form of duopoly whereby the brand and the generic can divide any monopoly profits between them. A settlement between a branded pharmaceutical firm and the first-filing generic firm effectively immunizes even a very weak patent from challenge for the period covered by the delayed entry agreement plus 180 days.

B. Scholarly Debate Over Analytical Frameworks

U.S. antitrust jurisprudence reveals diverse scholarly approaches on antitrust regulation of reverse payment settlements. The analytical frameworks proposed particularly vary in the necessary burden of proof to establish antitrust claims. For example, Herbert Hovenkamp, Mark Janis, and Mark A. Lemley characterize reverse payment settlements as an agreement which “itself looks like an antitrust violation but the presence of [Intellectual Property] rights might absolve it . . . .” They assert that the legality of reverse payment settlements depends on the patent’s validity. In other words, reverse payment settlements are “pro-competitive if, but only if, the patent in question is valid and infringed.” Under this broad conceptualization, they envision a reverse payment as consisting of two specific elements of threshold value to the patentee: (1) “the cost of continued litigation” and (2) “the value of eliminating competition that the patentee could not expect ex ante to exclude after trial.” According to the authors, a patentee certain of prevailing in infringement litigation is likely to pay an infringement defendant up to reasonably anticipated litigation costs simply to avoid a lengthy litigation process. However, a patentee doubtful about the validity of its patent has an incentive to share part of the value of its monopoly with an infringing defendant to exclude the potential competition which would occur after trial absent the settlement. Paying compensation for delayed entry, which corresponds to a

40. See Edlin et al., supra note 35, at 607.
43. See id. at 1725.
44. Id.
45. Id. at 1758.
46. Id. at 1759.
47. Id.
patentee’s chance of losing a suit, will ensure the full monopoly for the negotiated term without generic competition. Consequently, it follows that an exclusion payment that is more than saved litigation costs is anticompetitive, and any excessive payment represents a patentee’s chance of losing a suit. In short, Hovenkamp, Janis, and Lemley propose that reverse payment settlements should be presumptively illegal unless the branded firm establishes: “(1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit.”

Carl Shapiro has charted a slightly different course from the analytical framework proposed by Hovenkamp, Janis, and Lemley—even though he has reached a similar conclusion that reverse payments in excess of avoided litigation costs signal that the settlements are likely to be anticompetitive. Shapiro envisages patent settlements profitably favorable to the settling parties as permissible so long as such settlements do not lead to the decrease of the overall level of competition that would have arisen from ongoing litigation. However, according to Shapiro’s argument, reverse payments in exchange for delayed entry, in general, produce lower consumer surplus than would be expected absent the settlements. In this context, Shapiro observes that, unlike traditional patent settlements, reverse payment settlements are presumed to be illegal even if he concedes that an antitrust inquiry in practice may invite extensive consideration of additional factors such as the strength of the patent, risk aversion, and asymmetric information.

By contrast, Daniel Crane views the analytical model of Hovenkamp, Janis, and Lemley as undermining the social benefits of patent settlements and only focusing on the social costs of such settlements. Crane criticizes this model as

48. See id.
49. Id.
50. Id. at 1759.
52. Id. at 396.
53. Id. at 396–97, 410.
54. Id. at 397, 408.
“mak[ing] per se illegal many socially beneficial settlements.”

Crane proposes that reverse payment settlements should be presumed to be lawful, and the antitrust plaintiff should bear the burden of showing illegality of the settlements. According to Crane’s argument, the key factor for evaluating whether exclusionary payments are anticompetitive is “the ex ante likelihood that the defendant would be excluded from the market if the case was finally adjudicated.” Crane opines that requiring the settling parties to retain the necessary documents to prove that the settlement in question is not anticompetitive will result in little social cost given those parties are generally “in the best position to produce information justifying the settlement.” Crane, however, stresses that placing the burden of proof on antitrust defendants in an antitrust suit will chill patent dispute settlements.

Thomas F. Cotter takes an approach occupying the middle ground. More specifically, Cotter generally agrees with the quick look rule of reason approach endorsed by Hovenkamp, Janis, and Lemley. Under this approach, once an antitrust plaintiff shows the settlement involves reverse payments, the burden of demonstrating the legality of the reverse payment settlement is shifted to the settling parties and antitrust defendants. Furthermore, Cotter’s model is mostly in line with that of Hovenkamp, Janis, and Lemley in that the size of reverse payments is related to the strength of the relevant patent case. However, Cotter’s model does not admit the relatively narrow suggestion of Hovenkamp, Janis, and Lemley that reverse payments are lawful only when they properly reflect avoided litigation costs. But rather Cotter argues that reverse payment settlements are often considered to be rational dispute resolution instruments for the settling parties. Recognizing the existence of some social benefits of reverse payment settlements, Cotter critically opines that Hovenkamp, Janis, and Lemley “might
not view the elimination of reverse payment settlements as a huge loss . . . .”67 He calls into question their idea that an alternative to exclusion payments is a settlement in which the patentee permits the infringement defendant to obtain a license to market.68 According to Cotter’s explanation, the patentee may or may not prefer reverse payments to licenses, but its preference solely depends upon its rational decision-making based on the strength and value of the patent.69 Namely, that forecasted higher payoffs will lead to seeking a route to reverse payments.70 In this context, Cotter emphasizes that prohibiting the parties from seeking reverse payments would reduce the value of patents, which “reflect a legislative judgment that their benefits exceed their costs.”71

Therefore, Cotter proposes that the parties are allowed to have more leeway for employing reverse payments under the more stringent rule, which permits antitrust scrutiny only when the size of reverse payments is far beyond merely saved litigation costs.72 Specifically, Cotter notes that the patent is still likely to be valid and infringed when the size of the reverse payment is higher than avoided litigation costs but lower than the potential loss which, absent the settlement, the infringing defendant would suffer from the court granting an injunction.73 As such, Cotter’s model contains an infringement “defendant’s potential loss” cap on the number of reverse payments, which is higher than an “avoided litigation costs” cap proposed by the model of Hovenkamp, Janis, and Lemley.74 Therefore, Cotter’s model allows the settling parties and antitrust defendants to bear a relatively alleviated burden of proving that the patent is valid and infringed, and consequently, reverse payments are not anticompetitive.75 Accordingly, it seems that Cotter takes a stance slightly more favorable to antitrust defendants than Hovenkamp, Janis, and Lemley.76 On the other hand, Cotter presents a negative view of the scope of the patent approach employed by a majority of appeals courts

67. Id. at 1809 (“It may be that the marginal social benefit of tolerating such settlements is low, given their potential abuse and given the existence of an alternative settlement structure that would be less susceptible to abuse, but the evidence is not so clear.”).
68. Id. at 1808–11.
69. Id.
70. Id.
71. Id. at 1809–10.
72. Id. at 1814.
73. Id.
74. Id.
75. Id.
76. Compare id., with Hovenkamp et al., supra note 42.
in antitrust cases before *Actavis.* 77 Under this approach, in the absence of sham litigation (such as a frivolous or abusive lawsuit based on objectively meritless infringement claims or fraud in obtaining the patent from a regulatory agency) reverse payment settlements are immune from antitrust attack unless they have anticompetitive effects beyond the exclusionary zone of the patent. 78 Cotter stresses that the scope of the patent approach may create a huge safe harbor for the settling parties by “permit[ting] too many anticompetitive settlements to escape scrutiny.” 79

Henry N. Butler and Jeffrey Paul Jarosch argue for the full-scale rule of reason in antitrust inquiries into reverse payment settlements. 80 They argue that both the per se rule and the quick look rule of reason are not appropriate for antitrust scrutiny over reverse payment settlements because such rules are adoptable only when the challenged conduct at issue takes on an obviously anticompetitive nature. 81 They propose that the full-scale rule of reason is the appropriate approach for evaluating the legality of a reverse payment settlement because it is “not a type of agreement that ‘lack[s] any redeeming virtue,’” but rather it has an anticompetitive or procompetitive effect on competition depending on market conditions and specific contexts in which such a settlement occurs. 82 They argue that even if the size of the reverse payment serves as a strong indicator of whether the settlement is procompetitive or anticompetitive, it cannot become a sole determinant factor. 83 For effectively formulating the rule of reason analysis, Butler and Jarosch ask the court to examine six factors as proposed in determining “whether a given reverse payment is procompetitive, anticompetitive, or simply neutral.” 84 The factors are: “1) Market power; 2) The entrance date allowed by the reverse-payment settlement; 3) The relative size of the reverse payment; 4) The ANDA filer’s ability to market the drug without a reverse payment; 5) Sham

77. Cotter, supra note 61, at 1811.
78. See id.
79. Id. (noting that an infringement suit, even with a small chance of winning, may not be a sham but “a settlement based upon such a low probability . . . .” Such cases result in overall reduced consumer welfare).
81. Id. at 85–86.
82. Id. (citation omitted) (noting that both the per se rule and the quick look rule of reason set a high bar for an antitrust defendant to establish that conduct is not anticompetitive).
83. Id. at 115.
84. Id.
First, a reverse payment settlement is not anticompetitive if the branded firm does not have market power, and therefore it has little incentive to pay the generic firm to delay market entry. Second, the reverse payment settlement is not likely to be anticompetitive if the negotiated entry date thereof is far after the date on which the patent expires. Third, while a relatively large reverse payment strongly suggests that the settlement is anticompetitive, such a payment represents compensation for the generic firm’s covenant not to compete with the branded firm, asymmetry in bargaining power between the two firms, or the intention of the branded firm to avoid the potential risk of losing the infringement suit. Fourth, the fact that the generic firm lacks marketing ability without the reverse payment indicates that it has no anticompetitive effect because it can increase competition by allowing the generic firm to enter the market. Fifth, an infringement suit taking on objectively baseless sham litigation indicates that the reverse payment settlement is anticompetitive. Sixth, “[i]nequitable or severely unbalanced side deals” in bad faith, which are particularly intended to hide a reverse payment for delayed entry, suggest that they are anticompetitive. Proposing such factors, Butler and Jarosch emphasize the superiority of the traditional full-scale rule of reason. They note that both per se and quick look rules create significant error costs in requiring too little antitrust scrutiny while acknowledging that the rule of reason may, at the other extreme, create error costs in requiring too many antitrust inquiries. However, their arguments lead to the conclusion that the former rules are inferior to the latter, particularly in that they have more potential to create errors that “outweigh judicial efficiencies” than the traditional rule of reason as its potential errors can be mitigated by carefully examining the proposed six factors.
C. Case Law Governing Reverse Payment Settlements

In 2013, the U.S. Supreme Court rendered its first decision identifying the criteria for evaluating the legality of reverse payment settlements. The Court’s holding in Actavis represented a milestone in the establishment of antitrust jurisprudence on the regulation of reverse payment settlements. Indeed, Actavis marked a significant turning point in judicial perspectives of reverse payment settlements. The most substantive contribution of the Actavis decision is that the rule of reason was declared a governing rule for the antitrust analysis of reverse payment settlements. The rule of reason serves as a normative framework for intensive antitrust analysis under separate consideration of diverse factors such as market power retained by the antitrust defendant and anticompetitive effect of the practice in question. Consequently, further clarification and elaboration on the antitrust rules of reverse payment settlements can be made possible by the rule of reason.

The Actavis decision, however, created a controversy by leaving unanswered multiple crucial questions, which have been raised in subsequent judicial decisions. Accordingly, it seems that post-Actavis discussions of reverse payment settlements in U.S. antitrust jurisprudence have focused on evaluating the functional effectiveness of the Actavis rules by determining whether they can serve as the most up-to-date supreme rules, and have fine-tuned the Actavis rules to the extent that they can secure general applicability in diverse real-world settings. For instance, several subsequent cases invited the controversial question of whether financial consideration in a form other than typical cash payments is subject to the Actavis rules in the antitrust analysis. Notably, the key antitrust issues central to post-Actavis discussions are of normative importance—particularly in demarcating the anticompetitive zone of reverse payment settlements. Next, the Article discusses the essence of the landmark Actavis decision and then the rule development in post-Actavis cases.

96. See id.
97. See id.
98. Id. at 141.
99. Id. at 159.
100. See supra Part I.
101. See supra Part I.
102. See supra Part I.
103. See supra Part I.
1. The Essence of the Landmark Actavis Decision

    a. Factual background. Facing the long-standing circuit split, the U.S. Supreme Court in Actavis provided overarching criteria for evaluating the legality of reverse payment settlements.\textsuperscript{104} Actavis represented a milestone in eliminating the conflict of disparate approaches in pre-Actavis cases. Actavis concerned reverse payment settlements between the manufacturer, Solvay Pharmaceuticals, Inc., of the pioneer drug AndroGel and three other manufacturers of the generic version of AndroGel: Actavis (formerly known as Watson Pharmaceuticals, Inc.), Paddock Laboratories, Inc. (Paddock), and Par Pharmaceutical Companies (Par).\textsuperscript{105} Actavis was the first Paragraph IV ANDA file entitled to 180-day exclusivity while Paddock was the next filer.\textsuperscript{106} Par did not file an ANDA separately but agreed to share the litigation costs with Paddock in exchange for part of potential profits if Paddock obtained approval for its generic drug.\textsuperscript{107}

    Solvay filed a New Drug Approval (NDA) for AndroGel in April 1999 and obtained FDA approval in February 2000.\textsuperscript{108} In January 2003, Solvay was granted the relevant patent for AndroGel, which expired in August 2020.\textsuperscript{109} In May 2003, while Solvay’s AndroGel was being sold in the market, Actavis filed an ANDA for its generic version of AndroGel with the FDA, subsequently followed by a separate ANDA filed by Paddock for its own generic.\textsuperscript{110} Actavis and Paddock argued that Solvay’s patent was invalid and therefore their generic drugs did not infringe it.\textsuperscript{111} Solvay responded by timely filing a patent infringement lawsuit against Actavis and Paddock.\textsuperscript{112} Par joined forces with Paddock for litigation.\textsuperscript{113} In the midst of the lawsuit, the statutory 30-month stay period expired in January 2006 and, shortly after, the FDA approved Actavis’ generic product.\textsuperscript{114} This meant that Actavis could have immediately placed its generic drug in the market.
competing only with Solvay during 180 days of statutory exclusivity. 115 Subsequently, Paddock could have entered the market immediately after the expiration of Actavis’ exclusivity. 116 Paddock’s market entry would have been further expedited if the district court had ruled on Actavis’ and Paddock’s claims even before the expiration of exclusivity and had found the patent invalid or not infringed. 117 Therefore, faced with the possibility of losing its monopoly due to robust generic competition, Solvay opted to discontinue litigation and rather settle patent disputes with those generic competitors by creating pay-for-delay settlement agreements in which Solvay agreed to pay each of Actavis, Paddock, and Par a significant amount of money in exchange for their promises not to bring their generics to market until August 2015, 65 months before Solvay’s patent expired. 118

The Federal Trade Commission (FTC) filed an antitrust suit against Solvay, Actavis, Par, and Paddock, but the district court granted the defendants’ motion to dismiss FTC’s antitrust complaint for failure to state a claim for relief and held the reverse payment settlements at issue did not exceed the legitimate scope of the patent. 119 The Court of Appeals for the Eleventh Circuit in Federal Trade Commission v. Watson Pharmaceuticals, Inc., affirmed the trial court’s dismissal of the FTC’s complaint under the scope of the patent approach which was used in key precedents: Valley Drug Co. v. Geneva Pharmaceuticals, Inc, Schering-Plough Corp. v. Federal Trade Commission, and Andrx Pharmaceuticals, Inc. v. Elan Corp., PLC. 120 Those precedents established that “absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.” 121 The Eleventh Circuit distinguished the settlements at issue from the other typical type of reverse payment settlements. 122 The Eleventh Circuit stated that while “antitrust laws typically prohibit agreements where one company pays a potential competitor not to enter the market, . . . reverse

115. See id.
116. See id. at 1304–05.
117. Id.
118. Id. at 1305 (stating that Actavis forecasted that its generic product would be sold for about 25 percent of the price of the branded AndroGel and thereby the sales of branded AndroGel would decrease by 90 percent).
119. Id. at 1306.
120. Id. at 1312–15 (citing Valley Drug Co. v. Genova Pharm., Inc., 344 F.3d 1294 (11th Cir. 2003); Schering-Plough Corp. v. Fed. Trade Comm’n, 402 F.3d 1056 (11th Cir. 2005); Andrx Pharmas., Inc. v. Elan Corp., 421 F.3d 1227 (11th Cir. 2005)).
121. Watson Pharm., 677 F.3d at 1312.
122. See id. at 1312–15.
payment settlements of patent litigation presented atypical cases because ‘one of
the parties own[s] a patent.’”123 The scope of the patent approach may well grant a
high degree of immunity for reverse payment settlements from antitrust
condemnation because, as the circuit said, their legitimacy would rely only on the
exclusionary potential of the patent, which would likely be considered present and
comprehensive unless the patent is ultimately found invalid.124 The circuit court
held that in the light of a general public policy favoring patent dispute settlements,
antitrust scrutiny over reverse payment settlements would not include adjudication
as to the validity of the patent.125

b. Key features of reverse payment settlements. The Actavis Court began its
reasoning by conceptualizing reverse payment settlements. The Court
distinguished reverse payment settlements from traditional forms of patent dispute
settlements.126 The Court interpreted reverse payment settlements as being featured
by their unusual pattern in which “a party with no claim for damages (something
that is usually true of a paragraph IV litigation defendant) walks away with money
simply so it will stay away from the patentee’s market.”127 This pattern is far
different from what is seen in traditional form of settlements in which “a party with
a claim (or counterclaim) for damages receives a sum equal to or less than the value
of its claim.”128 The Court viewed this abnormal pattern of value transfer as
speaking to the existence of collusion between the parties for anticompetitive
objectives: namely buying out potential generic competitors and sharing the
monopoly profits at the cost of consumers.129

In other words, if the patentee confers upon the generic challenger a
substantial degree of compensation beyond traditional settlement considerations,
that may “provide strong evidence that the patentee seeks to induce the generic
challenger to abandon its claim with a share of its monopoly profits that would
otherwise be lost in the competitive market.”130 The Court conceived the
anticompetitive nature of reverse payment settlements as stemming from “payment

123. Id. at 1307 (quoting Valley Drug, 344 F.3d at 1304).
124. Id. at 1313–14.
677 F.3d at 1313–14).
126. Id. at 141, 152.
127. Id. at 152.
128. Id.
129. Id. at 153–54.
130. Id. at 154.
in return for staying out of the market,” namely exclusion payment, because the settlements involving this payment “keeps prices at patentee-set levels, potentially producing the full patent-related . . . monopoly return [as shared by] . . . the challenged patentee and the patent challenger.” 131 In legitimate patent dispute settlements, the generic party would not be simply paid off to stay out of the market because—in the absence of collusion—all the terms and conditions for settlements would be expected to be determined entirely by bargaining process based on each party’s separate assessment at arm’s length of the prospective outcome of the patent infringement suit. 132

c. Rule of reason treatment of reverse payment settlements. The U.S. Supreme Court in Actavis granted certiorari, sought by the FTC, because it deemed hearing and deciding on the criteria for evaluating the legality of reverse payment settlements necessary to eliminate discrepancy among the circuits. 133 Although the Actavis Court was in line with the Eleventh Circuit on the point that antitrust litigation over reverse payment settlements should not involve “an inquiry into the merits of the patent suit,” it casted doubt on the validity of the circuit’s reasoning. 134 The Actavis Court refused to employ the scope of the patent test and furthermore declined to hold that the settlements at issue were per se illegal or presumptively unlawful. 135 Instead, the Court turned to the traditional rule of reason analysis of reverse payment settlements with particular emphasis on the size of the reverse payment. 136

By doing so the Actavis Court charted a middle course where at one extreme reverse payment settlements could be deemed nearly automatically lawful so long as their anticompetitive effect was considered within the purview of exclusionary potential of the patent, and at the other extreme, they could be found more likely than not per se illegal or at least presumed illegal as horizontal market division agreements. 137 In general, antitrust analysis under the rule of reason requires “a showing of (1) power sufficient to warrant a conclusion of plausible competitive

131. Id.
132. See Hovenkamp et al., supra note 42, at 1756–63.
134. See Aaron Edlin et al., Activating Actavis, ANTITRUST, Fall 2013, at 16, 19; Actavis, 570 U.S. at 156–58 (“[I]t is normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham”).
136. Id. at 159.
harm; (2) a restraint that threatens to reduce output or increase price; and (3) that is not justified by efficiencies or some other redeeming virtue.” 138 The Actavis Court did not depart from any of these principles. 139 Rather it allowed the lower courts to structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences. 140

d. Five guiding considerations for the rule of reason analysis. In articulating the contours of the rule of reason analysis, the Actavis Court presented five sets of key considerations. 141 These served to distinguish the Court’s approach from that which the Eleventh Circuit took in employing the scope of the patent test. 142 Provided below is the essence of those five considerations.

First, reverse payment settlements have the:

“potential for genuine adverse effects on competition.” The payment in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product. 143

Reverse payments allow both the patentee and the generic challenger to earn profits at the expense of consumers. 144 Monopoly profits shared by both parties would constitute consumer savings but for reverse payment settlements. 145 Furthermore, the regulatory approval scheme under the Hatch-Waxman Act would reduce incentives for other potential competitors to challenge the patent even if high reverse payments may signal that the patentee is dubious about the strength

139. Id.
140. Actavis, 570 U.S. at 159–60.
141. Id. at 153–58.
142. Id. at 153.
143. Id. at 153–54 (internal citation omitted).
144. Id. at 154.
145. Id.
of its patent.\textsuperscript{146} Potential competitors would be less motivated than the first challenger to demur to the validity of the patent because they are not entitled to the 180-day exclusivity period, they would have to wait for roughly 30 months before receiving FDA approval, and winning subsequent litigation with the result that the patent is invalid or not infringed would remove the barrier to final regulatory approval for not only the challenger but \textit{all} potential competitors.\textsuperscript{147}

Second, the anticompetitive consequence may prove justified if “[t]he reverse payment . . . may amount to no more than a rough approximation of the litigation expenses saved through the settlement [and] compensation for other services that the generic has promised to perform . . . .”\textsuperscript{148} Hence, an antitrust defendant’s showing of legitimate justification under the rule of reason may be able to eliminate an antitrust concern arising from “a patentee . . . using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.”\textsuperscript{149}

Third, the size of reverse payments may point to whether the patentee holds market power to “work unjustified anticompetitive harm . . . .”\textsuperscript{150} A firm without market power would not pay its competitor to stay out of the market because doing so could not appreciably change the competitive situation and therefore the firm would not significantly increase the markup of its brand-name drug product.\textsuperscript{151}

Fourth, antitrust scrutiny over reverse payment settlements does not necessarily require patent validity litigation.\textsuperscript{152} A large, unjustified reverse payment implies that the patentee has significant doubts about the strength of its claims of patent validity and infringement.\textsuperscript{153} A patentee pays the generic challenger simply to avoid the risk of post litigation generic competition and set monopoly prices for its product.\textsuperscript{154} It is noted that the size of the reverse payment

\begin{itemize}
\item \textsuperscript{146} \textit{Id.} at 155 (“[A] reverse payment settlement with the first filer . . . ‘removes from consideration the most motivated challenger, and the one closest to introducing competition.’”) (quoting C. Scott Hemphill, \textit{Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem}, 81 N.Y.U. L. REV. 1553, 1579 (2006)).
\item \textsuperscript{147} \textit{Id.} at 155–56.
\item \textsuperscript{148} \textit{Id.} at 156.
\item \textsuperscript{149} \textit{Id.}
\item \textsuperscript{150} \textit{Id.} at 157.
\item \textsuperscript{151} See Edlin et al., \textit{supra} note 134, at 17.
\item \textsuperscript{152} \textit{Actavis}, 570 U.S. at 157.
\item \textsuperscript{153} \textit{Id.}
\item \textsuperscript{154} \textit{Id.}
\end{itemize}
is a surrogate for both a patent’s weakness and market power, and large payments to prevent even a small risk of competition constitutes an antitrust violation.155

Fifth, although reverse payment settlements are not permissible as anticompetitive practices as long as they include exclusion payment, litigating parties can still seek other forms of justified patent dispute settlements.156 For instance, they are allowed to enter into a settlement which enables a prepatent-expiration generic entry without turning to reverse payments.157

These five pillars of specific considerations constitute the backbone underpinning the Court’s analysis.158 Those considerations, in their entirety, serve as a well-marked guidance by which the Court could properly navigate in the rule of reason analysis.159 The Court stresses the methodological significance of this approach stating “these considerations, taken together, outweigh the single strong consideration—the desirability of settlements—that led the Eleventh Circuit to provide near-automatic antitrust immunity to reverse payment settlements.”160

e. Key implications of the Actavis decision. A close look at the Actavis decision provides several significant implications for antitrust analysis of reverse payment settlements. First, the Actavis Court’s recourse to the rule of reason analysis represents reconciliation of strict antitrust liability and near-automatic antitrust immunity.161 Indeed, the Actavis Court explicitly refused to apply an overly lenient legal rule—the scope of the patent test—by stating that reverse payment settlements even within the exclusionary zone of the patent are not always immune from antitrust scrutiny.162 The Court reached this conclusion because the patent may or may not be valid and even a valid patent did not allow the patent holder to exclude a non-infringer from competition.163 The Court’s analysis shows that “[a] large settlement exclusion payment disproportionate to litigation risk can be unlawful under antitrust’s rule of reason, without inquiry into whether the patent is actually invalid or not infringed, and even if the settlement agreement does not

155. Id. at 158.
156. Id.
157. Id.
158. Id. at 153.
159. Id. at 158.
160. Id.
162. Actavis, 570 U.S. at 146.
163. Id. at 147.
go ‘beyond the scope’ of the patent’s nominal coverage.” The *Actavis* version of the rule of reason is not only in direct variance with the per se rule, but it is also out of line with the so-called quick look rule of reason, a truncated rule of reason, under which the challenged practices are deemed “presumptively unlawful.”

Unlike the per se, quick look, and rule of reason tests, the traditional full scale rule of reason analysis involves a detailed factual inquiry into the nature and the effect of the practice concerned and market circumstances. Albeit basically standing on the conventional rule of reason, the *Actavis* Court altered it in two ways: (1) allowing the antitrust plaintiff to establish a prima facie case by initially showing that there was a large, unjustified reverse payment for delay, that is, a payment to prevent the risk of potential generic competition; and (2) limiting the possibility for viable antitrust defenses. Hence, the burden of proof imposed on an antitrust plaintiff is significantly alleviated to the extent that antitrust scrutiny obviates the necessity of a separate showing of both market power and anticompetitive harm to competition. Given that the rigorous full-scale rule of reason analysis requires a thorough market power assessment predicated upon the market definition/market share paradigm and competitive effect analysis, one may argue that the *Actavis* Court tweaked the typical version of the rule of reason to the appreciable degree.

However, the Court analysis should be construed as properly conforming to the normal structure of the conventional rule of reason analysis. The Court stated “‘[t]here is always something of a sliding scale in appraising reasonableness’ and as such ‘the quality of proof required should vary with the circumstances.’” This statement, and others, are interpreted to clearly manifest the Court’s intention to turn antitrust scrutiny to the basic contours of the traditional rule of reason. In

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164. *AREEDA & HOVENKAMP, supra* note 138, at 455.
165. *See Actavis*, 570 U.S. at 158–59. The FTC has employed a quick look approach in the antitrust investigation concerning reverse payment settlements, in particular, in the pharmaceutical sector. *See* AM. BAR ASS’N, ANTITRUST LAW DEVELOPMENT 1082–83 (7th ed., ABA Book Publ’g 2012). While the U.S. Department of Justice (DOJ) has regulated reverse payment settlements in non-pharmaceutical sectors, it has also taken a quick look approach. *Id.*
166. *See* FED. TRADE COMM’N & U.S. DEP’T OF JUST., ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS § 1.2 (2000).
167. *Actavis*, 570 U.S. at 157; *see* Edlin et al., *supra* note 134, at 20; Davis & McEwan, *supra* note 137, at 577.
169. *Id.; AM. BAR ASS’N, INTELLECTUAL PROPERTY AND ANTITRUST HANDBOOK* 165 (2d ed., ABA Book Publ’g 2015).
conducting the conventional rule of reason analysis the Court appears to have envisaged the two-part analysis of market power and anticompetitive effect as being superfluous, from both the procedural and substantive perspective, to antitrust probes into pay-for-delay settlements.\textsuperscript{171} In sum, the \textit{Actavis} version of rule of reason analysis is not a deviation from but rather in a proper fashion reflective of the traditional rule of reason approach.\textsuperscript{172} It is noteworthy that the Third Circuit in \textit{King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.} held that “[t]he \textit{Actavis} Court provided initial guidance on how to structure [traditional] rule of reason litigation in the reverse payment context.”\textsuperscript{173}

Second, \textit{Actavis} holds that patent policy has very limited relevance in determining antitrust legality of reverse payment settlements.\textsuperscript{174} The \textit{Actavis} Court stated that patent policy might be taken into account as well as the antitrust policy for the purpose of antitrust analysis.\textsuperscript{175} The Court rejected the Eleventh Circuit’s scope of the patent approach based on the measurement of the settlements’ competitive harm against the patent policy.\textsuperscript{176} Rather, it made clear that antitrust scrutiny required an accommodation of both patent and antitrust policies, so “finding challenged terms and conditions unlawful unless patent law policy offsets the antitrust law policy strongly favoring competition.”\textsuperscript{177} It is noted that the patent-related policy underlying this case is “eliminating unwarranted patent grants so the public will not ‘continually be required to pay tribute to would-be monopolists without need or justification.’”\textsuperscript{178} Thus, the antitrust analysis in the context of reverse payment settlements may raise the policy question of “whether ‘the patent statute specifically gives a right’ to restrain competition in the manner challenged . . . .”\textsuperscript{179} A close look at \textit{Actavis} shows that the Court failed to find legitimate statutory patent justifications for countervailing anticompetitive effects of reverse payment settlements at issue.\textsuperscript{180} Hence, the Court found that the

\begin{itemize}
\item \textsuperscript{171} See \textcite{Davis & McEwan, supra note 137, at 577.}
\item \textsuperscript{172} The U.S. Court of Appeals for the Third Circuit in \textit{King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.} held that the trial court “mistook . . . [the \textit{Actavis} analysis] as a redefinition of the ‘rule of reason’ itself. But the general contours of the rule of reason [in \textit{Actavis} are well-mapped.” 791 F.3d 388, 411 (3d Cir. 2015).
\item \textsuperscript{173} \textit{Id.} at 412.
\item \textsuperscript{174} \textit{Actavis}, 570 U.S. at 148.
\item \textsuperscript{175} \textit{Id.}
\item \textsuperscript{176} \textit{Id.}
\item \textsuperscript{177} \textit{Id.} at 151.
\item \textsuperscript{178} \textit{Id.} (quoting \textcite{Lear, Inc. v. Adkins, 395 U.S. 653, 670 (1969)}).
\item \textsuperscript{179} \textit{Id.} at 148 (quoting \textcite{United States v. Line Materials Co., 333 U.S. 287, 311 (1948)}).
\item \textsuperscript{180} See \textit{id.}.
\end{itemize}
settlements fell short of “the lawful restraint on trade of the patent monopoly and [rather within] the illegal restraint prohibited broadly by the Sherman Act.”

Third, even if the Court admitted the limited relevance of the patent policy to the antitrust question, the Actavis Court denied directly assessing the strength of a patent i.e., the validity of a patent, in deciding on patent-related antitrust matters. This is in part because as the Court stated, “[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival.” The Actavis Court characterized litigating the patent strength in the antitrust case as “demonstrat[ing] what would have happened to competition in the absence of the settlement.” This simply means a de facto consolidation of patent and antitrust litigation—which otherwise appears extraneous to each other. The Eleventh Circuit pessimistically described this likely dual-trial as “attempt[ing] to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to judgment.” “[A] patent mini-trial inside an antitrust case” might allow a defendant to establish the legality of reverse payment settlements by showing that the patent is likely to be found valid or infringed. The Actavis Court seemed to take a negative stance in examining the patent strength in antitrust scrutiny by stating that “[i]t is normally not necessary to litigate patent validity to answer the antitrust question.” Indeed, the Court’s analysis reveals the supremacy of the size of payment approach over the patent-strength approach. In sum, the Actavis Court insulated an antitrust analysis of reverse payment settlements from direct and detailed inquiries into the patent’s strength. The Court declined to subordinate antitrust issues to patent issues especially where the challenged conduct was not explicitly allowed under the Patent Act. From this standpoint the Court stated that the FTC was not required to “litigate the patent’s validity, empirically demonstrate the virtues or vices of the patent system, present

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181. Id. (quoting Line Material Co., 333 U.S. at 311).
182. Id. at 157.
183. Id.
184. Id. at 153.
185. See id.
186. Fed. Trade Comm’n v. Watson Pharm., Inc., 677 F.3d 1298, 1315 (11th Cir. 2012) (comparing “deciding a patent case within an antitrust case about the settlement of the patent case” to a “turducken” task).
187. See Edlin et al., supra note 134, at 19.
188. Actavis, 570 U.S. at 157.
189. See Edlin et al., supra note 134, at 19.
190. AREEDA & HOVENKAMP, supra note 138, at 454.
every possible supporting fact or refute every possible pro-defense theory.”191 Actavis holds that the strength of the patent can be inferred from the size of payment without separate inquiries.192 In the frame of the Court’s analysis, the size of the payment itself answers “patent-law-based questions about patent quality” so long as such a payment reflects the parties’ market-based business judgment about the perceived merits of the patent case.193 The size of the payment as a workable proxy for the patent strength clears antitrust scrutiny of “a detailed exploration of the validity of the patent itself.”194

Fourth, Actavis holds that risk aversion cannot justify payments for delay.195 In other words, the necessity of avoiding the risk of the patent being found invalid or not infringed cannot offset adverse effects of reverse payment settlements on competition.196 It is worth reiterating that the Actavis Court clarified that both market power and anticompetitive effects could be inferred from large reverse payments transcending the aggregate of avoided litigation costs and compensation for the fair market value of any services provided by the generic firm.197 A firm with market power typically enjoys high price-cost margins and has a strong incentive to protect them.198 Likewise, a branded firm enjoying market power may attribute part of such power to the valid patent which functionally excludes the use of patented invention without permission, such as granting license.199 But, facing the generic competitors’ patent challenge, a branded firm unsure of winning the litigation is likely to settle patent disputes by paying those challengers in order to avoid the risk of the patent being found invalid or not infringed.200 Otherwise, the court’s judgment finding the patent invalid or not infringed would open the door of market entry for the generic firms in the wings.201 Payments—effectively work as a sufficiently attractive inducement to the generic firms’ commitments to stay out of the market—will amount to more than the branded firm’s prospective

192. Id. at 158.
193. AREEDA & HOVENKAMP, supra note 138, at 467.
194. Actavis, 570 U.S. at 158.
195. Id.
196. Id.
197. Id.; see also Edlin et al., supra note 35, at 590.
198. See Edlin et al., supra note 134, at 17; AREEDA & HOVENKAMP, supra note 138, at 216.
200. See id. at 156.
201. Id.
litigation expense and compensation for any services performed by the generic firms. As the Court highlighted, large reverse payments serve to eliminate potential competition and thereby strengthen the firm’s monopoly by allowing it to maintain supracompetitive prices to the detriment of consumers. This is why the Court emphasized that risk aversion could not serve as a legitimate justification for large reverse payments. In short, the risk of patent invalidity is not extraneous to, but fundamentally associated with, the risk of competition. Large payments reflect the underlying intention of the branded firm—when seriously dubious of the patent strength—to avert the risk of potential competition that would be expected to occur following litigation. Accordingly, reverse payment settlements destroy not only the risk of patent invalidity but also the risk of competition. The Court stated that preventing even a de minimis risk of competition constituted an antitrust violation in that it distorts competition and harms consumer welfare. Actavis establishes that risk aversion cannot sever the logical link between large reverse payments and market power and anticompetitive effects.

Fifth, while structuring the rule of reason analysis, the Actavis Court devised an unconventional but direct method for examining market power and anticompetitive effects. The Court used a large reverse payment as direct proof of market power and competitive harm. It seems clear from an evidentiary standpoint the Court perceived “more abbreviated proof than ordinarily attends the full rule of reason was available for both power and anticompetitive effects.” While the rule of reason analysis requires a comprehensive consideration of market circumstances and variables, the Court instead turned to non-market-based proof under “the structured and circumscribed rule of reason approach . . . .” That is, the Court focused on the defendant’s conduct itself, namely payment for delay, rather than assessing the structure of the relevant market and the defendant’s

202. Id.
203. Id. at 156–57.
204. See id.
205. See id. at 157–58.
206. Id. at 157.
207. Id.
208. See id. at 157–58.
209. See id. at 158.
210. See id.
212. See Edlin et al., supra note 134, at 17.
performance in that market.\textsuperscript{213} According to the traditional rule of reason, defining the relevant market and identifying its structure enables an evaluation of “the plausibility of antitrust claims that the defendants’ business conduct will create, enlarge, or prolong market power.”\textsuperscript{214} However, the Court conceived the size of the reverse payment as a workable surrogate for market power and anticompetitive effects in the light that a large and unjustified payment induces injurious collusion between the patentee and challenger and harms competition.\textsuperscript{215} As the Court stated, a large payment itself signifies the patentee’s serious doubt about the patent’s validity and functions as a financial consideration from the patentee which intends to circumvent market competition and rather maximize its profit by setting the price above the competitive level through under-the-table dealings with the challenger.\textsuperscript{216} Here, it is worth reiterating the Court’s view that the patentee’s economic interest of avoiding even a small risk of patent invalidity cannot work as “redeeming virtues” countervailing the competitive harm resulting from the large payment which “likely seeks to prevent the risk of competition.”\textsuperscript{217} This view leads to the underlying connotation that any small reverse payment for risk aversion may not justify anticompetitive consequences derived therefrom.\textsuperscript{218} This is even though the payment is considered commercially reasonable from the patentee’s perspective because it does not exceed the patentee’s anticipated value of monopoly profits over the remaining period of the patent term.\textsuperscript{219} In articulating the meaning of the large and unjustified payment, the Court provided an appropriate benchmark for the size of the reverse payment.\textsuperscript{220} It noted that “the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.”\textsuperscript{221} It should be noted that “the \textit{Actavis} Court did not hold that a large reverse payment is dispositive of antitrust liability, nor that a patent guarantees market power.”\textsuperscript{222} Nevertheless, the Court’s view has normative overtones that “the size and circumstances of the reverse payment are

\begin{thebibliography}{222}
\bibitem{actavis} See \textit{Actavis}, 570 U.S. at 153–60.
\bibitem{areeda} \textit{Areeea & Hovenkamp, supra} note 138, at 243.
\bibitem{actavis2} \textit{Actavis}, 570 U.S. at 157–58.
\bibitem{id2} \textit{Id.} at 157.
\bibitem{id} \textit{Id.} at 156–57.
\bibitem{id3} \textit{See id.}
\bibitem{id4} \textit{See id.}
\bibitem{id5} \textit{Id.} at 159.
\bibitem{id6} \textit{Id.}
\bibitem{aggrenox} \textit{In re Aggrenox Antitrust Litig.}, 199 F. Supp. 3d 662, 665 (D. Conn. 2016).
\end{thebibliography}
suggestive of the market power conferred by the patent . . . but the ability to profitably charge supracompetitive prices over a sustained period (which ability the reverse payment may be calculated to preserve) is conclusive of market power, by definition.”

2. Rule Development in the Post-Actavis Cases

The Actavis Court’s conclusion relied heavily on the size of the reverse payment as a surrogate for patent weakness, for lost competition, and as a proxy for market power. The Court emphasized the size of the payment “as the key to understanding the settling parties’ likely motivations and the settlement’s potential anticompetitive effects.” The Court repeatedly uses “the terms ‘unexplained’ or ‘unjustified’ to modify ‘large reverse payments . . . .’” This suggests that such payments may not be illegal “if appropriately justified, and that the burden is on the defendant to justify (i.e., explain) them.” The Court provides five sets of considerations for examining reverse payment settlements in antitrust context. These factors create a well-marked roadmap, by which factfinders can properly navigate in investigating the legality of the settlements concerned.

However, the Court does not make clear critical issues such as when the reverse payment is not large and in what circumstances the payment is justified. Furthermore, the Court declined to establish the specific framework for the proper rule of reason analysis. The Court did not answer two key questions: “what evidence creates a sufficient inference of ‘likely anticompetitive effects,’ thereby shifting the burden to the defendant . . . [and] what justifications the courts will admit to rebut the inference.” Without a reasonable degree of clarification provided, the Court entrusted and directed the lower courts to “structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every

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223. Id. at 665–66.
224. Aaron Edlin et al., Actavis and Error Costs: A Reply to Critics, ANTITRUST SOURCE, Oct. 2014, at 1, 1; Actavis, 570 U.S. at 156–58.
225. Edlin et al., supra note 224, at 3.
226. Id. at 4.
227. Id. (emphasis in original).
228. Actavis, 570 U.S. at 153–58.
229. See id.
230. See Edlin et al., supra note 224, at 3–4.
231. See id.
232. Id.
possible fact or theory irrespective of the minimal light it may shed on the basic question . . . .”

The post-Actavis landscape hints particularly at two aspects of Actavis inference: “what constitutes a ‘large and unjustified’ reverse payment” and how to structure the antitrust’s rule of reason. Court attempts to provide further elaboration and clarification to answer these sophisticated questions the Actavis Court left open.

a. Defining a large and unjustified reverse payment. Fine-tuning the concept of a large and unjustified reverse payment includes analyzing three issues: what constitutes a “payment,” what is a “large payment,” and what is an “unjustified payment.” The post-Actavis landscape reveals the growing trends to treat such issues, which are critical in antitrust inquiry, on a case-by-case basis.

i. Defining the payment. At the immediate aftermath of Actavis several trial courts narrowly defined the scope of a payment only to include cash payments. However, these decisions were reversed by appellate courts upholding that the Actavis inference was construed as including both cash and non-cash payments. The U.S. Court of Appeals for the Third Circuit in In re Lamictal Direct Purchaser Antitrust Litigation viewed no-Authorized-Generic agreements

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233. Actavis, 570 U.S. at 159–60 (“We therefore leave to the lower courts the structuring of the present rule of reason antitrust litigation.”).
234. Lisa Jose Fales et al., Welcome to the Wild, Wild West: Actavis Five Years Later, ANTITRUST, Summer 2018, at 18, 18.
235. See id.
236. See id.
237. See id.
239. King Drug, 791 F.3d at 403 (“We do not believe Actavis’ holding can be limited to reverse payments of cash. For the following reasons, we think that a no-AG agreement, when it represents an unexplained large transfer of value from the patent holder to the alleged infringer, may be subject to antitrust scrutiny under the rule of reason.”); Loestrin, 814 F.3d at 549 (“[T]he Supreme Court recognized that a disguised above-market deal, in which a brand manufacturer effectively overpays a generic manufacturer for services rendered, may qualify as a reverse payment subject to antitrust scrutiny and militates against limiting the Supreme Court’s decision to pure cash payments.”).
as falling under *Actavis’* scope and the U.S. Court of Appeals for the First Circuit in *In re Loestrin, 24 FE Antitrust Litigation* and *In re Nexium (Esomeprazole) Antitrust Litigation* ruled to the same effect.\textsuperscript{240} As previously explained, an AG is a generic version of a drug, which is authorized by the branded firm “under its own FDA approval.”\textsuperscript{241} Under the Hatch-Waxman framework, an AG is allowed to be launched even during the 180-day exclusivity period.\textsuperscript{242} A no-Authorized-Generic agreement is a promise by the branded not to introduce an AG.\textsuperscript{243} Both the First and Third Circuit decisions in particular have paved a consensus to the notion that antitrust scrutiny attaches to both cash and non-cash payments alike.\textsuperscript{244} Given the pitfalls of reading *Actavis* to the contrary, it is reasonable to conclude that “the form of the reverse payment does not matter for the purposes of the Actavis Inference.”\textsuperscript{245} Indeed, this conclusion is more plausible because the *Actavis* Court did not explicitly or implicitly deny that its holding applied to non-cash payments.\textsuperscript{246} Limiting antitrust scrutiny only to monetary reverse payments will result in other forms of payments receiving antitrust acquittal when antitrust defendants “take the obvious cue to structure their settlements in ways that avoid

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\textsuperscript{240} *King Drug*, 791 F.3d at 404–05 (“[N]o-AG agreements are likely to present the same types of problems as reverse payments of cash . . . [and] may be of great monetary value to . . . the first-filing generic . . . . The anticompetitive consequences of this pay-for-delay may be as harmful as those resulting from reverse payments of cash. If the brand uses a no-AG agreement to induce the generic to abandon the patent fight, the chance of dissolving a questionable patent vanishes . . . .”); *Loestrin*, 814 F.3d at 550 (“[A]ntitrust scrutiny attaches not only to pure cash reverse payments, but to other forms of reverse payment that induce the generic to abandon a patent challenge, which unreasonably eliminates competition at the expense of consumers. Moreover, this approach is consistent with antitrust law, which has consistently prioritized substance over form.”); *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 41 (1st Cir. 2016) (“[I]mproper reverse payments may take the form of ‘non-monetary’ advantages. The language and logic of *Actavis* dictated that outcome.” (internal citation omitted)).

\textsuperscript{241} Edlin et al., *supra* note 35, at 595.

\textsuperscript{242} *Id.*

\textsuperscript{243} *Id.* at 596.

\textsuperscript{244} See Fales et al., *supra* note 234, at 18.

\textsuperscript{245} Edlin et al., *supra* note 35, at 593.

\textsuperscript{246} Davis & McEwan, *supra* note 137, at 570–71 (criticizing a few courts for their counterintuitive views suggesting that *Actavis* holdings do not extend to non-cash payments because the dissent in *Actavis* said to the contrary and stating “[g]iven the great care with which the Justices and their clerks write, it is implausible that the majority would have failed to contradict the dissent—and indeed would have confirmed the dissent’s view—if instead it meant to limit reverse payments to cash.”).
transfers profits that the brand would have made from its AG to the generic because it enables the latter to enjoy higher prices in generic monopoly in lieu of generic duopoly without further generic competition.\textsuperscript{250} Non-cash payments may not be limited to no-AG agreements,\textsuperscript{251} but include other business arrangements such as joint development and co-promotion agreements.\textsuperscript{252}

\begin{footnotesize}
\begin{enumerate}
\item[247.] In re Loestrin 24 FE Antitrust Litig., 814 F.3d 538, 548–50 (1st Cir. 2016) ("[A] narrow construction of \textit{Actavis} will give drug manufacturers carte blanche to negotiate anticompetitive settlements so long as they involve non-cash reverse payments . . . .").
\item[248.] \textit{Id.} at 548.
\item[249.] Edlin et al., supra note 35, at 597–98 ("[T]he no-AG provision is more harmful to competition than a cash settlement of the same magnitude. The cash settlement operates as a mere wealth transfer from the brand to the generic, delaying entry but with little impact on generic output once generic entry takes place. By contrast, the no-AG provision compensates the independent generic in a more sinister fashion, by giving it protection from competition that would otherwise occur and thus keeping up prices at consumers’ expense.").
\item[250.] In re Opana ER Antitrust Litig., 162 F. Supp. 3d 704, 717 (N.D. Ill. 2016).
\item[251.] King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 408 (3d Cir. 2015) (noting that the non-cash nature of no-AG agreements does not alter the need that it must be subject to the balance test); In re Lipitor Antitrust Litig., 868 F.3d 231, 252 (3d Cir. 2017) (affirming “that a reverse payment underlying an \textit{Actavis} antitrust claim need not be in cash form.” And “that a no-AG agreement, when it represents an unexplained large transfer of value from the patent holder to the alleged infringer, may be subject to antitrust scrutiny under the rule of reason.”).
\item[252.] In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14-md-02503, 2018 WL 563144, at *3 (D. Mass. Jan. 25, 2018) (stating the parties entered into a joint development agreement); \textit{Opana}, 162 F. Supp. 3d at 713, 716–17 (“Although the form and amount of that payment were contingent on future occurrences, taking the Plaintiffs’ allegations as true, it was certain at the time of the . . . [s]ettlement that the [party] would receive . . . from $33 to $49 million under the No AG-Agreement and an additional $10 million under the [Development and Co-Promotion Agreement].”); King Drug Co. of Florence, Inc. v. Cephalon, Inc., 88 F. Supp. 3d 402, 408–09 (E.D. Pa. 2015) (stating the parties entered into a collaboration agreement and an option and exclusivity agreement).
\end{enumerate}
\end{footnotesize}
ii. Defining the size of payment. The Actavis Court emphasized the size of the payment as the key to understanding the parties’ likely motivations and the settlement’s potential anticompetitive effects. However, the Court did not explicitly define the size of payment but only requires that a reverse payment must be in excessive of anticipated litigation costs or fair value for services performed by the generic. The vague and superficial term coupled with the simplistic approach by the Court created further complexity and controversy over whether Actavis itself is self-contained or leaves room for further elaboration or clarification with the introduction of complementary benchmarks. The Court notes, “the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.” It is said “the weight of post-Actavis decisions has tilted heavily against an analysis that is simply a comparison to saved litigation costs.” Indeed, many subsequent decisions pointed out that anticipated litigation costs themselves were not dispositive and therefore necessitated additional considerations. For instance, the court in In re Aggrenox Antitrust Litigation stated that “payments smaller than avoided litigation costs are presumptively not large and unexplained under Actavis, and represent a de facto safe harbor, and also that [more importantly] payments exceeding avoided litigation costs are not automatically deemed unlawful for that reason alone.”

It is noteworthy that a payment large enough to trigger an Actavis inference can be calibrated against “the expected profit[s] to be earned by [the generic] if it

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253. Edlin et al., supra note 224, at 3.
255. See id.
256. Id. at 159.
257. Fales et al., supra note 234, at 18.
258. In re Aggrenox Antitrust Litig., 94 F. Supp. 3d 224, 243 (D. Conn. 2015) (“Even if the payments exceed avoided litigation costs, the Actavis factors . . . still matter.”); King Drug Co. of Florence, Inc. v. Cephalon, Inc., 88 F. Supp. 3d 402, 417 (E.D. Pa. 2015) (“[A] reverse payment is sufficiently large if it exceeds saved litigation costs and a reasonable jury could find that the payment was significant enough to induce a generic challenger to abandon its patent claim.”); In re K-Dur Antitrust Litig., No. 01-cv-1652 (SRC)(CLW), 2016 WL 755623, at *12 (D.N.J. Feb. 25, 2016) (implying a large payment exists if “the brand-name company paid the generic company consideration of some kind, and that the consideration exchanged in the settlement exceeded the estimated cost of litigation and the costs of other services and products . . . .”); In re Opana ER Antitrust Litig., 162 F. Supp. 3d 704, 718 (N.D. Ill. 2016) (“A ‘large’
had prevailed in the patent litigation.” 260 The court in Apotex, Inc. v. Cephalon, Inc. alluded to the need to consider whether the reverse payment comes close to, or exceeds, such expected generic profits. 261 Controversy results from Actavis’ silence about the specific threshold against which the size of payment is measured. 262 On top of that, another aspect of complexity that may deserve attention is when non-monetary payment is concerned. One may wonder if the valuation of the non-monetary payment is necessary for the appropriate comparison. The United States District Court for the District of New Jersey in In re Effexor XR Antitrust Litigation asserted that “the non-monetary payment must be converted to a reliable estimate of its monetary value so that it may be analyzed against the Actavis factors.” 263 The court viewed a non-monetary payment as including “something of value that can be converted to a concrete, tangible or defined amount which yields a reliable estimate of a monetary payment.” 264 The district court in In re Lipitor Antitrust Litigation (Lipitor I) reaffirmed its view in Effexor XR by stating that Actavis’ holding is contemplated as emphasizing cash payments and therefore a reliable monetary estimate must be identified to determine whether the value of a non-monetary payment is large enough to fall within Actavis. 265 However, this finding is completely at odds with what can be inferred from Actavis. The Actavis Court does not explicitly require an antitrust plaintiff to show such “a reliable cash value” of the payment as the district court insisted, 266 instead it must just be found to be “above reasonably anticipated

payment is anything more than the value of the avoided litigation costs plus any other services provided from the generic to the brand manufacturer.”.

259. Aggrenox, 94 F. Supp. 3d at 243.
261. Id.
262. See id.
264. Id. at *19.
265. In re Lipitor Antitrust Litig. (Lipitor I), 46 F. Supp. 3d 523, 543 (D.N.J. 2014) (“[I]t is true that Actavis never indicated that a reverse payment had to be a cash payment; but it is also true that Actavis emphasized cash payments. In applying Actavis here, the non-monetary payment must be converted to a reliable estimate of its monetary value so that it may be analyzed against the Actavis factors such as whether it is ‘large’ once the subtraction of legal fees and other services provided by generics occurs.”).
266. Effexor XR, 2014 WL 4988410, at *20 (“[W]here a non-monetary payment is alleged in an antitrust suit, the pleading must demonstrate the reliable foundation showing a reliable cash value of the non-monetary payment through the use of more facts upon which Plaintiff depends.”).
litigation costs to trigger the Actavis Inference.”267 Accordingly, the Third Circuit rejected the findings of the district court in both cases.268 The court found the district court ruled against the plaintiff without conducting various calculations as necessitated by the reliable monetary estimate.269 As such, determining whether or not the payment is large must be “a circumstance and fact-driven inquiry devoid of bright lines.”270

### iii. Defining the unjustified payment.

The Actavis thresholds tell that a reverse payment may be deemed justified if the payment does not exceed “a rough approximation of the litigation expense saved through the settlement. That payment may reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item . . . [or] traditional settlement considerations, such as avoided litigation costs or fair value for services,” or if it offers “any other convincing justification.”271 The Third Circuit in Lipitor II, however, read these four Actavis thresholds as illustrative and noted that Actavis does “not exclude other possible legitimate explanations from also justifying reverse payment settlement agreements.”272 Accordingly a question follows: what exemplifies other possible legitimate explanations? The Third Circuit in In re Wellbutrin XL Antitrust Litigation allusively dropped a hint.273 The court noted that a no-AG agreement could “be said to be unjustified in the sense of being unexplained . . . [because] it was not tied to the merits of the litigation . . . [and] was fixed at 180 days, regardless of who prevailed in the case . . . .”274 Nevertheless, the court mentioned the term “business judgment” and left room for further discussion of whether the sound exercise of business judgment can be considered a legitimate factor justifying the reverse payment.275

In re Solodyn (Minocycline Hydrochloride) Antitrust Litigation suggests a similar notion.276 The court sustained the defendant’s claims arguing that “whether the deal was commercially reasonable is relevant to whether the reverse payment

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267. Edlin et al., supra note 35, at 601.
269. Id. at 254.
270. Fales et al., supra note 234, at 18.
272. Lipitor II, 868 F.3d at 251.
274. Id. at 162.
275. Id. at 162 n.49.
was justified.”277 The court borrowed language from *Loestrin* reiterating: “[A]ntitrust litigation often requires an ‘elaborate inquiry into the reasonableness of a challenged business practice.’”278 The court accepted the notion of calibrating the payment from a business perspective to determine whether it is justified.279 Thus, the court advocated for the approach under which the payment is weighed against the commercial reasonableness benchmark.280 As such, the court stated “‘[w]hether a payment was large and unjustified,’ requires viewing the payment in the context of the facts of the case, which may include business considerations that are less tangible or quantifiable.”281

*Solodyn* also provides a useful insight into the concept of fair value.282 *Actavis* notes fair value for services as traditional settlement considerations do not create the same antitrust concern that the “patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.”283 The court in *Solodyn* declined the “narrow definition proposed by Plaintiffs,” arguing that “fair value requires ‘an arms-length, objective, market-based measurement’ of the services Impax promised to perform . . . .”284 Rather, in the court’s broader view, the brand’s perspective of future earnings relates to the calculation of fair value.285

b. **Structuring the antitrust’s rule of reason.** The Supreme Court in *Actavis* adopted the rule of reason but rejected the quick look approach which the Court found to be “appropriate only where ‘an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.’”286 Under the rule of reason, a large reverse payment, made in return for delayed generic entry, “is not irrefutable evidence of an anticompetitive settlement agreement, but it does leave the defendants with some explaining to do.”287 As such, the rule of reason analysis poses two important questions: “what evidence creates a sufficient

277. *Id.* (emphasis added).
278. *Id.* (quoting *In re Loestrin 24 FE Antitrust Litig.*, 814 F.3d 538, 552 (1st Cir. 2016)).
279. *Id.*
280. *Id.*
281. *Id.* (citation omitted).
282. See *id.* at *4, *6.
285. *Id.* at *6.
inference of ‘likely anticompetitive effects,’ thereby shifting the burden to the defendant . . . [and] what justifications the courts will admit to rebut the inference.”

Despite the approach taken by the Court, the structure of the rule of reason in pay-for-delay contexts still remained wide-open because this task was left to the lower courts. The dissent viewed the majority as employing the “novel” approach where all the complex issues are shoehorned into “antitrust law’s amorphous rule of reason.”

This flexibility Actavis offers has yielded the counter-productive consequence of having lower courts themselves struggle to flesh such a novel approach out and wade into uncharted water. It was incumbent on the courts to navigate the rule of reason without deviation from Actavis’ guidance. The puzzle courts managed was the burden of proof framework needed to be reshaped in the structured rule of reason. In other words, courts’ opinions differed as to whether the antitrust plaintiff has a front-loaded burden to show the existence of a large and unjustified payment in order to trigger the rule of analysis.

A majority of courts appear to require the plaintiff to establish the existence of a large and unjustified payment as a precursor to the rule of reason analysis. One of the district courts favored placing a weighted initial burden on the plaintiff by noting that “[m]ost district courts read Actavis to hold that it is the ‘large and unjustified reverse payment’ that creates the anticompetitive concerns, and only after finding such a payment in the settlement may courts engage in the traditional rule of reason analysis.”

This approach was endorsed by both the First and Third Circuits. The First Circuit in Loestrin asserted that “the plaintiffs must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under Actavis.”

The Third Circuit in Lipitor credited the language of the First Circuit by noting that “[i]f plaintiffs do so, they may proceed to prove their allegations under the traditional antitrust rule of reason analysis.” Prior to Lipitor II, the Third Circuit in Smithkline Beecham held that under the structured rule of reason, the plaintiff must initially prove

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288. Id. at 3–4.
289. Actavis, 570 U.S. at 159–60.
290. Id. at 160–61 (Roberts, C.J., dissenting).
292. Id. at 1066.
293. In re Lipitor Antitrust Litig. (Lipitor II), 868 F.3d 231, 252 (3rd Cir. 2017); In re Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 552 (1st Cir. 2016).
294. Loestrin, 814 F.3d at 552.
295. Lipitor II, 868 F.3d at 252.
payment for delay and then the burden shifts to the defendant to show legitimate justifications.\textsuperscript{296}

By contrast, the district court in \textit{In re K-Dur Antitrust Litigation} favored the approach of incorporating the burden of alleging a large and unjustified payment into the rule of reason analysis.\textsuperscript{297} Stating that the \textit{Actavis} Court explicitly rejected the “quick look” approach, the court appears to read \textit{Actavis} to call for a pay-for-delay analysis under the genuine rule of reason without deviation.\textsuperscript{298} The court recognized that an asymmetry of information exists between the plaintiffs and defendants.\textsuperscript{299} Thus, in the court’s view, the fact that the defendant had better access to information about the value of the payments and the estimate of avoided litigations costs mitigates the plaintiffs’ initial burden of proof.\textsuperscript{300} In the framework that the court adopted, the plaintiffs bear the initial burden to establish a prima facie case by showing that there is a limit on generic entry and the branded drug companies compensated the generic companies.\textsuperscript{301} The burden then shifts to the defendants to present “evidence of litigations costs or valuable collateral products or services that might explain the compensation.”\textsuperscript{302} If the defendants proffer this evidence, the burden shifts a second time.\textsuperscript{303} The plaintiffs must demonstrate that “the compensation exceeds the reasonable value” of such litigation costs or other products or services.\textsuperscript{304} If the plaintiffs are successful, the defendants still have an opportunity to provide pro-competitive justifications, which in turn can be rebutted by the plaintiffs.\textsuperscript{305}

The legitimacy of this framework is questionable because it makes the rule of reason analysis too complex by creating too many segments, which allows too many burden shifts. Despite the treatment of the rule of reason as “something of a sliding scale,” the \textit{Actavis} Court made clear that the structured rule of reason

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\item King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 412 (3d Cir. 2015).
\item In re K-Dur Antitrust Litig., No. 01-cv-1652 (SRC)(CLW), 2016 WL 755623, at *12 (D.N.J. Feb. 25, 2016) (“Any sort of requirement for Plaintiffs to establish at the outset that a settlement payment in question was ‘large’ creates a threshold burden not delineated under the rule of reason.”).
\item Id.
\item Id.
\item Id. at *13.
\item Id.
\item Id. (quoting In re Cipro Cases I & II, 348 P.3d 845, 871 (Cal. 2015)).
\item Id.
\item Id. (quoting Cipro Cases, 348 P.3d at 871).
\item Id.
\end{enumerate}
\end{footnotesize}
should avoid not only “too abbreviated” theories but also too complex processes that require “consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences.”

In other words, the Court permits enough flexibility to streamline the rule of reason, to a greater or lesser degree, without detriment to its structure and direction. The Court also notes that “a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects . . . .” Actavis suggests antitrust analysis based on joint consideration of two factors: whether the payment is large and whether the payment is unjustified. In this sense, the Actavis-compatible framework should be the one placing on the plaintiff the initial burden to show both a large and unjustified payment under the rule of reason, not as a prerequisite to trigger the rule of reason.

Reading Actavis and other cases properly suggests the rule of reason approach that allocates burdens of production on balance but accommodates the proper use of shortcuts or surrogates if reasonably necessary in contrast with the quick look approach relieving the plaintiffs from the burden of establishing a large reverse payment. Thus, the plaintiff bears the burden of production to show a net payment in excess of avoided litigation costs and limitations on the generic’s ability to compete. The plaintiff’s demonstration of these things will satisfy the initial burden of proof under the rule of reason. The burden of proof to show the value of any other consideration, such as services, is placed on the defendant, who possesses better information. Unlike the quick look approach, the defendant is not deprived of the opportunity to rebut the prima facie case under the rule of reason. The defendant is free to “challenge the initial inference of an anticompetitive effect by, for example, presenting evidence that market power is lacking.” Thus, once the plaintiff initially shows that the branded company paid the generic companies more than the reasonably anticipated litigation expenses for

307. See id.
308. Id. at 158 (emphasis added).
309. See id.
310. Id.
311. Edlin et al., supra note 224, at 2–3.
312. Id. at 3.
313. Id. at 3–4.
314. Id. at 4.
315. Id.
316. Id. at 3 (noting the “ordinary rule-of-reason procedure leaves defendants free to present contrary evidence that challenges the inference of anticompetitive effect.”).
delayed entry, then the defendant must present contrary evidence that explains such a large payment.\footnote{Id. at 4 (“Allocating the burden to the defendant to provide justifications for a settlement also makes sense: it would be unreasonable and inefficient to expect a plaintiff to prove the absence of any convincing justification without requiring the defendants first to narrow the scope of the facts and justifications at issue by making their case.”).}

\section*{III. ANTITRUST THEORIES AND PRACTICES IN THE EUROPEAN UNION}

\subsection*{A. Legal Framework for Reverse Payment Regulation}

Revealing a sharp contrast with the U.S. regulatory system, the European Union does not have a regulatory scheme akin to the equivalent that is set out in the Hatch-Waxman Act.\footnote{See Council Regulation 726/2004, 2004 O.J. (L 136) 1 (EC).} In other words, in the European Union, marketing approval for new pharmaceuticals is not linked to the patenting system.\footnote{See id.} The directive of the European Parliament and of the Council of the European Union provides that marketing authorization shall not be “granted, refused, varied, suspended, withdrawn or revoked” on patent-related grounds such as submission of a certificate of patent invalidity or non-infringement.\footnote{See id. (“[L]aying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency”). The EC in its recent decision made it clear that either invalidity or non-infringement of a patent was not a requirement for a drug manufacturer to fulfill to obtain marketing approval in the European Union. See Case AT.39226—Lundbeck, Comm’n Decision, 2013 O.J. (C 3803) 211 (EC).} Thus, a drug manufacturer that seeks to obtain marketing approval in the European Union is just required to demonstrate the quality, safety, or efficacy of the drug that this approval is for.\footnote{Council Regulation 726/2004, art. 12, 2004 O.J. (L 136) 1 (EC).} However, it may be a hasty conclusion to assume that a patent on the new drug is generally subject to weaker protection in the European Union than the United States. This is particularly because, while a pioneer drug manufacturer in the European Union is normally granted up to 11 years of marketing exclusivity, a 3-to-5-year period of exclusivity is granted for a new drug in the United States.\footnote{In the European Union, a new drug manufacturer is granted eight years of data exclusivity and additionally two years of marketing exclusivity. The 10-year period of data and marketing exclusivity can be extended to a maximum of 11 years. The new drug manufacturer may enjoy monopoly profits for up to a total of 11 years of exclusivity. See Directive 2004/27/EC, of the European Parliament and of the Council of 31 March 2004 on the
Notably, the European Union has some history of antitrust scrutiny over reverse payment settlements, even if these settlements were not rare in a real-world setting.323 Facing a significant concern over these settlements, the European Commission (EC)—the European Union’s independent executive arm in charge of competition regulation—conducted a pharmaceutical sector inquiry in 2008,324 issued a Final Report in 2009, and published six subsequent Reports on the Monitoring of Patent Settlements—including the most recent version in 2015.325 These reports provide a meticulous analysis of the competitive relationship between branded and generic firms, and amongst branded firms by thoroughly examining a variety of competition issues, including reverse payment settlements.326

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<td>(No limitation on generic entry)</td>
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Table 1. EC Proposed Categorization of Patent Settlement Agreements

Community Code Relating to Medicinal Products for Human Use and Amending Council Directive 2001/83/EC, 2004 O.J. (L 136) 85. By comparison, the Hatch-Waxman Act provides that a five-year period of marketing exclusivity is granted to a new drug manufacturer for a new drug containing active ingredient which has never been approved by the U.S. Federal Food and Drug Administration (FDA). See 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii). Furthermore, the Act provides for three-year marketing exclusivity, which is granted for a new drug product containing an active ingredient that has been previously approved when the NDA includes reports of new clinical investigations essential to the approval of the application and conducted or sponsored by the NDA applicant. See id. §§ 355(c)(3)(E)(iii), (j)(5)(F)(iii).

323. Gürkaynak et al., supra note 24, at 141.
324. Id.
The 2009 EC Final Report indicates a categorization of patent settlements on the basis of two criteria: (a) whether the agreements in question limit the generic firm’s ability to launch its drug in the relevant market; and (b) whether there is any value transfer from the branded to the generic firm.327 Under this categorization, patent settlements which do not limit generic entry (category A) or include no value transfer from the branded to the generic firm (category B-I) are generally unlikely to be problematic under European competition law.328 By contrast, the

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<tr>
<td>Category B-II (Limitation on generic entry &amp; Value transfer from the branded firm)</td>
<td>Early generic entry No license (or no distribution agreement) granted the generic firm</td>
<td>Early generic entry License (or distribution agreement/supply agreement) granted to the generic firm</td>
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<td>No early generic entry License (or distribution agreement/supply agreement) granted to the generic firm</td>
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328. The sixth EC Monitoring Report indicates that patent settlements of specific types which would fall under category A or B-I might be subject to antitrust scrutiny. Commission 6th Report on the Monitoring of Patent Settlements, paras. 15–16 (Dec. 2, 2015) [hereinafter EC 6th Monitoring Report], https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report6_en.pdf [https://perma.cc/BWA2-8NP3]. They include unilateral conduct of the branded firm that might have caused generic delay, settlements concluded outside the exclusionary zone of the patent and settlements on the patent which the patent holder obtained from a regulatory agency in a fraudulent manner such as the provision of incorrect, misleading, or incomplete information. See id.
settlements which limit generic entry and include value transfer (category B-II) are more likely to be incompatible with European competition law and, therefore, highly subject to antitrust scrutiny.329

The Commission proposed categorization attempts to schematize how patent settlements may cross the line under the European competition law regime.330 However, it seems that this categorization, which invites two-prong consideration, is likely to be vulnerable to the criticism that it cannot properly capture the complex landscape of reverse payment settlements under the broad and ambiguous concepts: the limitation of generic entry and value transfer.331 Therefore, the conceptual loophole should be closed with further elaboration and clarification to enhance the practical effectiveness of this categorized scheme.

B. Case Law Governing Reverse Payment Settlements

While a number of complaints with respect to reverse payment settlements were lodged before the Commission, it adopted decisions in four cases to date: Lundbeck, Johnson & Johnson/Novartis, Perindopril (Servier), and most recently, Cephalon.332 Notably, Lundbeck is the first EC decision holding that reverse payment settlements were presumptively illegal under European competition


330. *Id.*

331. *See id.* at 269.

332. *See also OECD Committee on Competition Law and Policy Note on the Commission’s Recent Enforcement of EU Antitrust Rules in the Pharmaceutical Sector*, para. 22 (Jun. 12, 2014), https://one.oecd.org/document/DAF/COMP/WG(2014)62/En/pdf [https://perma.cc/PGX9-NXK6]. For Lundbeck, Johnson & Johnson/Novartis, Servier, and Cephalon, see respectively Case AT.39226—Lundbeck, Comm’n Decision, 2013 O.J. (C 3803) (EC); Case AT.39685—Fentanyl, Comm’n Decision, 2013 O.J. (C 8870) (EC); Case AT.39612—Perindopril (Servier), Comm’n Decision, 2014 O.J. (C 4955) (EC); Case AT.39686—Cephalon, Comm’n Decision, 2020 O.J. (C 8153) (EC). Different from Lundbeck and Servier, Johnson & Johnson/Novartis did not involve any intellectual property rights because the reverse payment settlement in question in that case did not take the form of a patent dispute settlement but was actually a co-promotion agreement between the U.S. pharmaceutical firm, Johnson & Johnson, and Swiss pharmaceutical firm, Novartis. The agreement allowed Johnson & Johnson to maximize its supra-competitive profits for sales of its brand-name drug Fentanyl in the Netherlands by requiring the Novartis to delay marketing its generic version of Fentanyl in return for significant monthly payments from Johnson & Johnson, which considerably exceeded the profits that the latter expected to earn if it would have entered the market. Notably, the Fentanyl patent held by Johnson & Johnson had already expired before both parties entered into a co-promotion agreement. Case AT.39685—Fentanyl, 2013 O.J. (C 8870).
law.\textsuperscript{333} \textit{Lundbeck} provided rudimentary normative guidance for antitrust analysis of reverse payment settlements under the two-prong test laid down in the 2009 EC Final Report.\textsuperscript{334} Likewise, \textit{Servier} also relied on this test and provided more detailed delineation of two elements: the limitation of generic entry and value transfer.\textsuperscript{335} But \textit{Servier} encompassed substantive discussions of competitive effects of challenged settlements beyond the reach of \textit{Lundbeck}.\textsuperscript{336} In other words, \textit{Servier} accommodated a substantial degree of methodological deviation from \textit{Lundbeck}, which adopted the by-object restriction approach, by turning to both by-object and by-effect restriction approaches.\textsuperscript{337}

1. Lundbeck Case

\textit{a. Factual background.} From a factual perspective, \textit{Lundbeck} is distinguished from \textit{Actavis} mainly in that before the pay-for-delay settlements at issue were concluded, Lundbeck’s patents for the pharmaceutical compound of antidepressant medicine citalopram and two original processes to manufacture citalopram had already expired in most European countries.\textsuperscript{338} However, Lundbeck still had a number of process patents, which provided it with limited protection over certain, but not all, new ways of producing citalopram to the extent that such patents would be found to be valid or infringed.\textsuperscript{339} The generic firms employing either the original production process or any production process, not protected by valid process patents, could freely enter the market with generic versions.\textsuperscript{340} While facing actual or potential generic entry, Lundbeck attempted to claim infringement of its valid process patents before national courts, and subsequently four generic firms responded by claiming noninfringement or invalidity of the patents.

\textsuperscript{333} See Case AT.39226—Lundbeck, 2013 O.J. (C 3803), para. 1397.
\textsuperscript{334} See id.
\textsuperscript{335} See Case AT.39612—Perindopril, 2014 O.J. (C 4955).
\textsuperscript{336} Id.
\textsuperscript{337} Compare Case AT.39226—Lundbeck, 2013 O.J. (C 3803), para. 624, with Case AT.39612—Perindopril (Servier), 2014 O.J. (C 4955).
\textsuperscript{339} See Case AT.39226—Lundbeck, 2013 O.J. (C 3803), para. 3.
\textsuperscript{340} Id.
concerned.\textsuperscript{341} In 2002, Lundbeck and generic firms entered into six reverse payment settlements, all but one of which were concluded before litigation started.\textsuperscript{342}

b. The general court's judgment. The general court upheld the Commission’s decision that reverse payment settlements fell afoul of EU competition law in that they constituted restriction of competition by object within the meaning of Article 101 of the Treaty on the Functioning of the European Union (TFEU).\textsuperscript{343} The approach taken by the general court was to articulate the contours of the basic question of whether reverse payment settlements between Lundbeck and other generic firms constituted by-object restriction of competition under EU competition law.\textsuperscript{344}

Taking this approach, the general court upheld the Commission’s decision finding the settlements at issue equivalent to market sharing or exclusion agreements within the meaning of Article 101.\textsuperscript{345} Article 101 prohibits collusive business practices that have either an anticompetitive object, or actual or potential anticompetitive effects.\textsuperscript{346} An antitrust analysis under an object-based approach does not necessarily invite inquiries into market power but, by contrast, an effect-based approach requires proof of market power in the relevant market to identify the existence of negative effects on competition.\textsuperscript{347} The general court in Lundbeck

\textsuperscript{341} Id. The four generic firms, which challenged the validity of Lundbeck’s patents, were Merck, Arrow, Alpharma, and Ranbaxy. See id; Lundbeck, ECLI:EU:T:2016:449, paras. 1–22.

\textsuperscript{342} See Case AT.39226—Lundbeck, 2013 O.J. (C 3803), para. 4. Lundbeck’s settlements with four generic firms included two settlements with Merck covering the United Kingdom and the European Economic Area (EEA) excluding the United Kingdom, two settlements with Arrow covering the United Kingdom and Denmark, one settlement with Alpharma covering the EEA, and one settlement with Ranbaxy covering the EEA. See id.; Lundbeck, ECLI:EU:T:2016:449, paras. 23–60. The EEA includes 28 EU Member States and three Member States of the European Free Trade Association (EFTA), namely, Iceland, Liechtenstein, and Norway. See Country Profiles, EUR. UNION, https://european-union.europa.eu/principles-countries-history/country-profiles_en [https://perma.cc/F35R-ABUJ]; Siri Veseth Meling & Andri Lúthersson, EEA Agreement, EFTA https://www.efta.int/eea/eea-agreement [https://perma.cc/Y8NK-X6HQ].

\textsuperscript{343} See Lundbeck, ECLI:EU:T:2016:449, para. 48.

\textsuperscript{344} See generally id.

\textsuperscript{345} See id. paras. 435–436.

\textsuperscript{346} See Consolidated Version of the Treaty on the Functioning of the European Union art. 101, 2012 O.J. (C 326) 47 [hereinafter TFEU].

did not conduct an effect analysis; rather, it focused on determining whether the settlements at issue were by their nature “injurious to the proper functioning of normal competition.”

The general court affirmed the Commission’s decision based on the following six facts: (1) Lundbeck and other generic firms were at least potential competitors in the relevant market at the moment when the settlements in question were concluded; (2) Lundbeck transferred significant value to generic firms in the settlements; (3) this transfer of value was a return for generics’ commitments to stay out of the market; (4) the transferred value amounted roughly to the profits generics would have earned if they had entered the market; (5) Lundbeck could not have obtained generic limitations on market entry by enforcing its valid process patents had it not been for the transfer of value; and (6) the settlements did not resolve any patent disputes but rather were simply to limit generic entry in that they included no commitment for Lundbeck to abstain from litigating patent infringement and no guarantee of later market access for generics. The general court stated:

the very existence of reverse [exclusion] payments and the disproportionate nature of those payments were relevant factors in establishing whether the agreements at issue constituted restrictions of competition ‘by object’ for the purpose of Article 101 . . . in that, by those payments, [Lundbeck] provided an incentive to the generic undertakings not to continue their independent efforts to enter the market.

However, the general court affirmed the Commission’s finding that the existence of the reverse payment did not always create an antitrust concern if the payment is: (i) “linked to the strength of the patent, as perceived by each of parties,” (ii) necessary to seek “an acceptable and legitimate solution,” and (iii) not inclusive of anticompetitive constraints intended to delay generic entry. Hence, the settlement may be found legitimate even though it contains a certain inducement to the generic limitation of the commercial behavior—such as an obligation not to produce the patented invention during the period of the patent term—so long as that limitation is “based on competing interests and directly

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349. See id. paras. 661, 824, 874, 962, 1013, 1087, 1174.
351. See id. at 350 (citing Case AT.39226—Lundbeck, 2013 O.J. (C 3803), paras. 638–639).
related to the strength of the patent, as perceived by each party."352 In the absence of the agreed inducement related to the issue of likely validity of the patent, the settlement is likely to include a limitation that balances disparate interests between the disputing parties—such a limitation will be less rigid than reasonably anticipated from each party’s assessment of the strength of the patent.353 Moreover, the payment from the branded or generic firm may be considered acceptable and legitimate to eliminate irrationality.354 For example, in the settlement, the generic firm may agree to its commercial limitations—including the withdrawal from the market and payment to compensate the branded firm for the damage—if the former had already entered the market and later the parties come to consider that there is a high likelihood of the patent being declared valid and infringed.355 On the contrary, the settlement may include a payment from the branded firms as compensation for the generic firm’s damage if it had already stayed out of the market and later the parties come to consider the high likelihood of patent invalidity or non-infringement.356 The general court viewed the Commission as having only found that it was the disproportionate nature of reverse payments coupled with other factors including: (i) that those payments amounted to the profit the generic firm anticipated earning in competition with the branded firm, (ii) that the settlements did not contain any assurance that the generic could permissibly launch its product in the market immediately upon the expiration of the settlement, or (iii) that commercial constraints in the settlements fell outside the scope of the patent that resulted in the conclusion that the settlements constituted restraints on competition by object.357

Furthermore, the general court decided on the issue of whether the amount of reverse payments was sufficiently high to induce the generic firms to accept the limitations on their autonomy and to reduce their incentives to enter the market with their generic products.358 Thus, it stressed that a key factor in finding an infringement of Article 101 was whether the size of reverse payments corresponded roughly to the profit expected by the generic firms if they had prevailed in litigation and entered the market, but not Lundbeck’s anticipated litigation costs.359 This notion is fairly akin to the Commission’s decision that “the

353. Id.
354. Id.
355. Id. para. 639.
356. Id.
358. See id. para. 644.
359. Id. para. 751.
higher the [branded firm] estimates the chance of its patent being found invalid or not infringed, and the higher the damage to the [branded firm] resulting from successful generic entry, the more money it will be willing to pay the generic [competitor] to avoid that risk.360 To avoid generic competition and protect monopoly profits, the firm—dubious of the strength of its patent—may be willing to pay the generic competitors a considerable sum of money that exceeds its prospective litigation costs. This may suffice to induce the generic firms to settle infringement litigation and stay out of the market.361 It should be noted that the agreed upon size of reverse payments should be one that makes both parties better off from an economic standpoint.362 The branded would be likely to enjoy monopoly profit without generic competition.363 Generic entry would reduce the branded profits by the profit the generics would gain and consumer savings resulting from generic competition.364 Therefore, the profit the generics could make from market entry will be lowered by consumer savings compared to the profit the branded would be likely to lose after generic entry.365 By sharing these consumer savings that would have existed in generic competition, both parties would gain extra profits under the settlement.366 A reverse payment that is sufficiently large enough to make both parties profitable would be an amount not less than—in practice, far beyond—the profit the generic firm could earn in the market absent the settlement and not more than loss in profits expected by the patentee in the event of generic entry.367 Where the risk of competition is inevitable and market monopoly is no longer feasible, the risk-aversive branded firm would be willing to pay potential competitors up to the amount of money it expects to lose if generic entry were to occur.368 The generic firms, likewise, would be willing to accept such payment exceeding the profit they anticipate making after entering the market.369 This quantitative threshold for qualified payments represents the asymmetry of risks borne by the parties and aligns their economic interests.370

361. See id.
362. See id. para. 643.
363. See id. para. 640.
364. See id. para. 644.
365. See id. para. 645.
366. See id. para. 646.
369. Id.
370. Id. paras. 370–371.
This asymmetry of risks arose because Lundbeck was “at risk of sustaining considerable and irreversible damage as a result of the infringement by the generic [firms], whereas the latter . . . faced little or no risk.”\footnote{371} Lundbeck and the generic firms contended that the payment from Lundbeck represented the pressure applied by the generic firms due to the asymmetry of risks.\footnote{372} They further asserted that this asymmetry properly explained why they sought “the most cost-effective or least risky course of action” by settling.\footnote{373} In fact, the parties’ behaviors in the face of the asymmetry of risks may be alleged to properly reflect economic rationality in that the asymmetry of risks vested the necessary and legitimate power in the generic firms to extract payments from Lundbeck and incentivized it to seek relatively more profitable behavior by paying the generic firms rather than facing litigation with a certain risk of generic entry which would have incurred more significant commercial damage.\footnote{374} Indeed, the asymmetry of risks may partly explain why Lundbeck decided to make such substantial payments to the generic firms in order to avoid the risk of generic entry, particularly because its pertinent patented drug is the flagship product representing most of its sales.\footnote{375} However, the general court found this asymmetry-of-risk argument insufficient to prove that large reverse payments constituted a legitimate mean of patent dispute settlements.\footnote{376} Thus, the asymmetry-of-risk argument was merely used to establish proof to the that Lundbeck succeeded in having its significant uncertainty as to the likely outcome of patent litigation completely converted to certainty of non-generic entry.\footnote{377} Even if it can be said that—as the Commission acknowledged—Lundbeck had commercially rational interests in eliminating uncertainty as to patent invalidity in order to avoid irreparable harm resulting from irreversible price falls as a consequence of unlawful market entry of the generic firms, those price falls are nothing more than legitimate “regulatory price cuts following the expiry of [a] patent [that] . . . constitute[s] a normal commercial risk which cannot justify the conclusion of anticompetitive agreements.”\footnote{378} Therefore, accepting the asymmetry-of-risk argument would be equal to considering that the parties could permissibly maintain supracompetitive prices for their products to the detriment of consumers even if they could not have obtained this outcome by the domestic

\footnote{371}{Id. para. 370.}
\footnote{372}{Id.}
\footnote{373}{Id. para. 380.}
\footnote{374}{Id. paras. 372, 379; Case AT.39226—Lundbeck, Comm’n Decision, 2013 O.J. (C 3803) 241, para. 704 (EC).}
\footnote{375}{Lundbeck, ECLI:EU:T:2016:449, para. 379.}
\footnote{376}{Id. para. 380.}
\footnote{377}{Id. para. 382.}
\footnote{378}{Id. para. 385.}
courts’ judgment finding the patents valid or infringed. The general court found this outcome contrary to the objectives of EU competition law mainly aimed at protecting consumer welfare. Indeed, payments to exclude actual or potential competitors and sharing monopoly profits resulting from the absence of generic drugs with those excluded competitors harms consumers of those drugs. Thus, reverse payment settlements constitute undue attempts to mitigate legitimate effects of legal rules—i.e., robust price competition with generics accruing from the expiration of the patent protection, which are considered excessively unfavorable to the parties—by seeking an anticompetitive means intended to ease competition and offset disadvantages on the pretext that those rules have created an imbalance that is detrimental to them.

As stated above, the general court also stressed that reverse payment settlements served to “replace the risks inherent in the normal competitive process and the state of uncertainty surrounding the validity of Lundbeck’s process patents . . . with the certainty that [the generic firms] would not enter the market during the terms of [the settlements] in return for significant reverse payments . . . ” In fact, this statement was in consonance with the Commission’s view that by the settlements, Lundbeck could avoid the risk of both patent invalidity and competition and instead obtain commercial certainty that the generic firms would neither enter the market nor seek a ruling of non-infringement or invalidity of the patent because significant reverse payments eliminated the incentives for the generic firms to enter or litigate. The Commission accentuated that it was the uncertainty as to the commercial behavior of the generic firms i.e., generic market entry, that reflects potential competition. Accordingly, it seems that the general court takes a stance similar to what the Actavis Court does on the risk aversion defense. But it is noteworthy that the Actavis Court did not flatly state that risk aversion could not justify reverse payments. Rather, it ambiguously stated that “even a small risk of invalidity [might] justify a large payment.” Theoretically,
the parties may defend by showing that the patentee paid the generic firms simply to avoid the risk of losing patent litigation but agreed to relatively early generic entry which will entail more competition than litigation. Indeed, the settlements allowing earlier generic entry than could be reasonably expected from litigation may strengthen competition for the benefit of consumers even if they include payments in excess of reasonably anticipated litigation costs.\textsuperscript{389} When would those settlements occur? Amidst uncertainty as to the likely outcome of litigation, a rising concern of the patent being declared invalid or not infringed may stimulate the patentee to pay generic challengers to circumvent the risk of even more competition that might accrue from a significantly unfavorable litigation outcome contrary to its expectations.\textsuperscript{390} In this case, consumers would be worse off, provided that the parties do not settle but continue to litigate patent disputes.\textsuperscript{391} Thus, consumers would be deprived of the opportunity to enjoy more competition through relatively early generic entry under the settlements than would be expected from litigation.\textsuperscript{392} It is also plausible that continued litigation may lead to a contrary result. Litigation would result in more competition if the patent was finally declared invalid not infringed against the parties’ expectation.\textsuperscript{393} As such, large payments can be justified by “even a small risk of invalidity” if the patentee is sufficiently risk-averse and the payment does not seek to prevent competition.\textsuperscript{394}

However, reverse exclusion payments distinguish \textit{Actavis} and \textit{Lundbeck} from the foregoing situation where the sufficiently risk-averse patentee may pay generic challengers to settle patent disputes, but consumers are made better off by being given access to more competitive market. Exclusion payments bring up an antitrust concern. The settlements containing exclusion payments eliminate the risk of invalidity and create the sloping playing field where competition does not remain intact any longer.\textsuperscript{395} Those settlements foreclose the generic firms in an anticompetitive manner and thereby reinforce the patentee’s monopoly to the detriment of consumers.\textsuperscript{396} The patentee may want to make exclusion payments to prevent the patent from being found invalid or not infringed and thereby avoid facing potential competition which would occur following litigation but for the settlement. Payments sufficiently attractive to the generic firms will be not less than—considerably more than, in practice—reasonably anticipated litigations

\textsuperscript{389} See Edlin et al., \textit{supra} note 134, at 20.
\textsuperscript{390} \textit{Id.} at 18.
\textsuperscript{391} \textit{Id.} at 20 n.51.
\textsuperscript{392} \textit{Id.} at 18.
\textsuperscript{393} \textit{Id.} at 17.
\textsuperscript{395} \textit{Id.}
\textsuperscript{396} \textit{Id.} at 158.
costs. Payments transcending litigation costs manipulate the reasonably assessed likely outcomes of litigation and distort the market which would be competitive without the settlements. 397 Unexplained large payments are intended to induce the parties to enter into the settlements whereby potential rivals are removed from competition and, therefore, the patent preserves its market power. 398 Hence, in settlements the agreed period of competition will be shorter than could be expected from the possibility of the patentee losing litigation. 399 This is why reverse payment settlements eliminating the risk of invalidity are construed as crossing the antitrust line by removing the risk of competition. 400 Accordingly the Actavis Court viewed the settlement to avoid even a small risk of competition as constituting anticompetitive harm. 401 It further noted that the parties could have settled patent disputes by agreeing to generic entry prior to the patent expiration without significant payments for delay. 402 The general court recognized the notion linking the size of payment to the risk of a judgment finding the patent invalid or not infringed. 403 It stated that “any form of coordination which deliberately substitut[ed] practical cooperation between [the parties to the disputes] for the risks of competition” was prohibited within the meaning of Article 101. 404 Thus, it found it anticompetitive to artificially reduce or eliminate the risk of potential competition stemming from the likely outcome of patent litigation fully, which would depend on the strength of patent. 405 This finding is interpreted to imply that the general court views the risk-aversion defense as being impermissible in antitrust proceedings. 406

Notwithstanding the factual differences and the jurisprudential gap, Actavis and Lundbeck seem to generally follow a convergent path in pay-for-delay antitrust regulation. The general court affirmed the EC’s finding by holding that reverse payment settlements inclusive of generic limitations on market entry in return for significant value transfers constituted “a buying-off of competition.” 407 The

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397. Edlin et al., supra note 134, at 19.
398. Id.
399. See id. at 17.
400. Id.
402. Id. at 158.
404. See id.
405. Id. para. 431.
406. Id. para. 442.
407. Id. para. 352.
general court found that the EC did not err in treating reverse payment settlements as being equivalent to market-sharing or exclusion agreements which were deemed the most serious restrictions of competition within the meaning of Article 101. The general court further found that those settlements eliminated competitive pressure which could be exerted by the generic firms in the market and thus restricted competition by object. It upheld the EC’s finding that reverse payment settlements were tantamount to market sharing or exclusion agreements which were the most serious restrictions of competition. It is noteworthy that the general court overtly denied the scope of the patent test, stating that the Actavis Court also adopted the same approach by rejecting this test as employed by some lower courts. The general court affirmed the Actavis Court’s finding that the fact the reverse payment settlements fell within the scope of the patent did not make them exempt from antitrust scrutiny.

It further made it clear that reverse payment settlements went beyond the specific subject matter of the intellectual property rights of Lundbeck, including the right to oppose infringements, but not the rights to exclude the generic firms from competition even if those settlements fell within the scope of Lundbeck’s patents. The general court stated that the exclusionary potential of the patent was confined to the comparable constraints which the patentee could seek by legitimately enforcing its patents through court rulings for the exclusive use of its patented invention. Thus, the exclusive power of the patent is not interpreted to shield the patentee from challenges by the generic competitors contesting the patent’s validity, in a view that such protection is contrary to “the public interest to eliminate any obstacle to economic activity, which may arise where a patent was granted in error [or weak].”

c. The Court of Justice’s judgment. The general court’s judgment in Lundbeck was appealed to the Court of Justice of the European Union (ECJ) which

408. Id. paras. 435, 765.
409. Id. para. 474.
410. Id. paras. 435, 765.
411. Id. paras. 492, 512.
412. Id.
413. Id. para. 495. The Actavis Court and the general court in Lundbeck share common views about the legitimate scope of the exclusive power of the patent. The Actavis Court stressed that the patent may “permit the patent owner to charge a higher-than-competitive price for the patented product . . . and even a valid patent confers no right to exclude products or processes that do not actually infringe.” Fed. Trade Comm’n v. Actavis, Inc., 570 U.S. 136, 148 (2013).
415. Id. para. 487.
is the highest court of the European Union. The ECJ entirely dismissed *Lundbeck* and others’ appeals against the general court’s judgment—upholding the European Commission’s 2013 pay-for-delay infringement decision. The ECJ confirmed its earlier judgment in the *Generics (UK) Ltd. v. Competition and Markets Authority (Paroxetine)* case, where it, for the first time, provided the analytical foundations regarding pay-for-delay agreements. The ECJ judgment has significant normative impacts on the development of antitrust rules on the legality of reverse payment settlements.

### i. Potential competition

Article 101(1) of the TFEU provides for both actual and potential competition. The analysis of potential competition requires consideration of market entry that has not yet occurred. The relevant question is whether the threat of entry is strong enough to affect the ability and incentives of existing market players to influence the relevant parameters of competition to their advantage. The question also follows as to whether, in reaction to a deterioration of the conditions of competition, one or more firms would undertake the costs involved in entering the relevant market within a relatively short period of time. Thus, the assessment of potential competition involves consideration of both the probability of entry and the timing of entry. According to the ECJ, in order to assess whether generic firms that were not present in a market were potential competitors of the branded firm that were already present in that market, the EC had to determine whether there were “real and concrete possibilities” of the generic firms entering that market and competing with the branded firm. The ECJ took account of whether generic firms had “a firm intention and an inherent ability to enter the market,” and “[did] not meet barriers to entry that are insurmountable.”

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417. *Id.*
419. *See TFEU, supra* note 346, art. 101(1).
421. *Id.*
422. *Id.*
manufacturers would have entered the market and that that entry would inevitably have been successful, but only that those manufacturers had real and concrete possibilities to enter the market. The ECJ found that the existence of a patent which protected the manufacturing process of an active ingredient that was in the public domain could not, as such, be regarded as an insurmountable barrier. Lundbeck’s compound patent had expired, and there were other processes available to produce citalopram that were non-infringing. In the ECJ’s view, the existence of potential competition must be assessed at the time of the settlement agreement’s conclusion. The fact that the patent at stake was validated in later litigation is extraneous to the assessment of whether the generic manufacturer is a potential competitor at the time of the settlement. Moreover, the ECJ found that a competition authority did not have to review the strength of the patent or the chance it would be found to be infringed.

The ECJ further noted that the presumption of patent validity, the uncertain outcome of disputes concerning validity, or the existence of interim injunctions did not undermine a finding that potential competition exists. The ECJ found generic manufacturers had a firm intention and an inherent ability to enter the market—as was evident with preparatory steps taken by those generics to obtain the required marketing authorizations, to challenge the process patents, and to create supply contracts with active pharmaceutical ingredients suppliers. These steps were sufficient to exert competitive pressure on Lundbeck, and therefore constitute relevant indication of the existence of potential competition between the generics and Lundbeck. As the ECJ pointed out, when there is not an insurmountable barrier to market entry, the existence of potential competition presupposes only that the generic manufacturer has taken sufficient preparatory steps to enter the market where the generic is readily capable of exerting

426. Id. para. 58.
428. Id. paras. 62–63.
429. Id. para. 66.
430. Id. paras. 68–69.
431. Id. para. 60.
432. Id. paras. 67–69.
433. Id. paras. 78, 86.
434. Id. paras. 86, 87.
competitive pressure on the branded medicine. The ECJ noted whether those steps will in fact be completed in due time or will be successful has no relevance.

ii. Restrictions of competition by object. Lundbeck challenged the accusation of the pay-for-delay agreements as “by object” restrictions of competition. Before the general court, Lundbeck relied on Actavis where the U.S. Supreme Court refused to apply a per se approach (similar to restrictions by object) and instead assessed the agreement under the rule of reason.

The distinction between restrictions by object and restrictions by effect is of jurisprudential significance in EU competition law. Once the plaintiff has established that an agreement has as its object the restriction of competition, there is no need to take account of the agreement’s concrete effects. In other words, according to Article 101 of the TFEU, no actual anticompetitive effects need to be demonstrated if the agreement has a manifest objective of restricting competition. A restriction by object exists when the coordination reveals a sufficient degree of harm to competition. In this respect, restriction of competition by object is analogous to the per se rule where the anticompetitive effect is irrefutably presumed. The per se rule applies when a trial court can say with confidence based on prior experience that the restraint will always or almost always have a net anti-competitive effect. The U.S. Supreme Court in Arizona v. Maricopa County Medical Society held that per se treatment is appropriate “[o]nce experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it.”

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435. Id. para. 84.
436. Id.
437. Id. para. 114.
439. Id. para. 432.
440. Id. paras. 436–437.
441. TFEU, supra note 346.
443. Id.
444. 457 U.S. 332, 344 (1982). “[T]here are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable and therefore illegal without elaborate inquiry as to the precise harm they have caused or the business excuse for their use.” N. Pac. Ry. Co. v. United States, 356 U.S. 1, 5 (1958); see also State Oil Co. v. Khan, 522 U.S. 3, 10 (1997).
In *Lundbeck*, payment that delays entry beyond the expiration of the patent was considered to be per se illegal. This finding is legitimate even in light of U.S. jurisprudence which holds “[d]uring the post-expiration period such an agreement is a naked restraint unprotected by any language in the Patent Act.”

*Lundbeck* contrasts factually with *Actavis* at least in the context of whether delayed entry goes beyond the expiration of patents at issue. That said, the two decisions converge with each other in that both courts followed a uniform standard in applying a different approach by factoring in whether the patent at issue was expired. The U.S. Supreme Court in *Actavis* required a rule of reason analysis because the pay-for-delay settlement concerned a delayed entry payment that permitted entry even before the patent’s expiration. The rule of reason raises a variety of issues and requires more elaborate treatment. The Court purported to apply the rule of reason but permitted truncated proof of both market power and anticompetitive effects from the size of an exclusion payment.

The ECJ reaffirmed its position that the concept of restriction by object must be interpreted narrowly and can only be applied to agreements that reveal a sufficient degree of harm to competition. This is at odds with the general court’s endorsement of a broader interpretation of the notion of restriction of competition by object. The general court took a stance that “potential competition may exist regardless of regulatory barriers to entry, in particular intellectual property rights, and that patent settlements may restrict competition by object regardless of whether they are within the scope of the patent at issue and of the counterfactual deviates from well-established principles.” By contrast, the ECJ confirmed its earlier finding in *Paroxetine* that an agreement to delay the market entry in exchange for monetary or non-monetary payment does not always constitute

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446. Id.
447. Id.
448. Id.
449. Id.
450. See id. at 125, 126, 153.
451. Id. at 125.
restriction by object.\textsuperscript{455} Thus, a case-by-case analysis is necessary. If there is an alternative rationale for the agreement, the agreement may not be treated as a restriction by object but a restriction by effect which requires further elaborate analysis like the rule of reason.

However, the ECJ found a restriction by object in this case because it was plain from the examination of the Lundbeck agreements that the reverse payment did not have any explanation other than to protect the parties’ commercial interest not to engage in competition.\textsuperscript{456} Thus, whether value transfers to potential entrants are sufficient to incentivize delayed or abandoned entry must be assessed on a case-by-case basis.\textsuperscript{457} However, the ECJ noted that there is no requirement that the value transfers should necessarily be greater than the profits which the generic manufacturer would have made if it had prevailed in patent litigation.\textsuperscript{458}

Furthermore, the ECJ considered that, prior to the agreements at issue, the parties were in dispute over whether Lundbeck’s new process patents could constitute the decisive basis of the non-entry commitment by the generics but were strong enough to prevent entry. The ECJ also found that the generics had made considerable efforts to prepare for their market entry and that they did not intend to desist from those efforts on account of Lundbeck’s new process patents.\textsuperscript{459} The general court concluded that it was “principally the size of the reverse payments to the generic undertaking which induced those undertakings to accept the limitations governing their behaviour . . . .”\textsuperscript{460} Accordingly, the ECJ found that the general court correctly characterized the agreements as restrictions by object.\textsuperscript{461}

The ECJ rejected Lundbeck’s arguments, particularly that the agreements were limited to the scope of new process patents and the agreements were exclusive of no-challenge clauses.\textsuperscript{462} As regards the former argument, the ECJ noted that agreements at issue “went beyond the specific subject matter of their intellectual property rights, which indeed included the right to oppose infringements, but not the right to conclude agreements by which actual or

\begin{itemize}
\item \textsuperscript{455} Lundbeck, ECLI:EU:C:2021:243, para. 113 (citing Case C-307/18, Generics (UK) Ltd v. Competition & Mkts. Auth., ECLI:EU:C:2020:52, paras. 84–85 (Jan. 30, 2020)).
\item \textsuperscript{456} Id. para. 114.
\item \textsuperscript{457} Id. para. 115.
\item \textsuperscript{458} Id.
\item \textsuperscript{459} Id. para. 117.
\item \textsuperscript{461} Lundbeck, ECLI:EU:C:2021:243, para. 141.
\item \textsuperscript{462} Id. paras. 120–135.
\end{itemize}
potential competitors were paid not to enter the market.” In response to the latter argument, the ECJ found that the generic manufacturers “had no incentive to challenge Lundbeck’s new process patents after concluding the agreements.” The ECJ held that “the reverse payments broadly corresponded to the profits that those manufacturers expected to make if they had entered the market or to the damages they could have been obtained if they had succeeded in litigation against Lundbeck . . . .”

The ECJ affirmed the general court’s judgment that it was clearly Lundbeck’s payments (and not the patents) that led the generics to accept the restrictions to their entry, and that Lundbeck failed to make substantiated assertions of any pro-competitive effects to show that the agreements are not restrictive of competition. Furthermore, the ECJ found that the restriction by object approach obviated the need to examine the “counterfactual scenario,” which purports to identify the effects of a concerted practice, in characterizing a given practice as a restriction by object. The ECJ noted there is a clear distinction between the concept of restriction by object and the concept of restriction by effect within the meaning of Article 101(1) of the TFEU. The ECJ made clear that the counterfactual scenario is examined to establish restrictions by effect in a way that the effects of a concerted practice is assessed in accordance with Article 101 when the analysis of that practice does not reveal a sufficient degree of harm to competition to be characterized as restrictions by object.

2. Servier Case

The Commission in Servier attempted to give a more detailed shape to the analytical methodology used to evaluate the legality of reverse payment settlements. The fact patterns in Servier and Lundbeck are nearly identical to each other. Servier’s compound patent for blockbuster blood pressure control medicine perindopril expired in 2003 for most countries upon the termination of the supplementary protection certificate which extended the initial patent term. Nonetheless, a number of process patents, so-called secondary patents, which were

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463. Id. para. 122.
464. Id. para. 135.
465. Id.
466. Id. paras. 136–137.
467. Id. para. 140.
468. Id.
469. Id. para. 139.
470. See Case AT.39612—Perindopril (Servier), Comm’n Decision, 2014 O.J. (C 4955) (EC). It is noted that the protection of Servier’s patent on perindopril in France and Italy expired in 2005 and 2009, respectively. Id. para. 96.
granted between 2004 and 2008, still afforded limited protection to Servier against
generic entry. When five generic firms attempted to challenge the weak
secondary patents of Servier, and came close to entering the market, Servier settled
patent disputes with each of those firms between 2005 and 2007. The settlements
at issue were characterized as reverse payment settlements because they contained
so-called exclusion payments.

The EC conducted a two-way antitrust analysis under the object-based
approach and effect-based approach. The Commission not only decided whether
reverse payment settlements between the branded firm Servier and other generic
firms by object or by effect constituted restraints of competition within the
meaning of Article 101 of the TFEU, but also examined whether Servier abused a
market dominant position pursuant to Article 102 of the Treaty.

a. Contractual limitations and value transfer. Servier provides an intensive
analysis of two key elements that should be considered for antitrust scrutiny over
reverse payment settlements: the limitation of generic entry and value transfer as
an inducement to the generic firm. First, the Commission expounded on two
types of contractual limitations: non-challenge obligations and non-compete
obligations. While the former prohibits the generic firm from challenging the
validity of a patent via patent litigation, the latter imposes on the generic firm “a
general limitation on [its] ability to pursue commercial activities, including by
seeking to enter the market with its generic version of the originator product in a
viable and timely manner.” Second, the Commission categorized the mode of
value transfer either as a one-way transfer of value from the branded to the generic
firm or a two-way transfer of value between the branded and generic firms. On
the one hand, in case of a one-way value transfer, the transferred value may be
represented by the total size of the unilateral payment by the branded firm. On
the other hand, in the case of a two-way value transfer, the reverse payment refers
to the difference between the value flowing from the branded to the generic firm

471. Id. para. 114.
472. Id. paras. 7, 19–40.
473. Id.
474. Id. para. 46.
475. Id. paras. 1184–1191.
476. Id. para. 1186.
477. Id.
478. Id. para. 1188.
479. Id.
and from the generic to the branded firm. The value transferred from the generic firm can be the fair market value of any services that the generic firm provided. It is noteworthy that if the value flowing from the branded firm is less than the value from the generic firm, the reverse payment may not serve as a genuine inducement to incentivize the generic firm to accept the limitation of its commercial activities but rather works as a counter-inducement to stimulate the generic firm to compete with the branded firm in the market.

b. Object-based approach under Article 101. The Commission made it clear that the exclusion payment itself was of an anticompetitive nature. It maintained its former position in Lundbeck, which was subsequently affirmed by the general court in 2016, and stressed that a patent conferred on the patentee the right to exclude an infringer, but not the right to conclude an anticompetitive settlement that pays actual or potential competitors to stay out of the market. Therefore, it is the means employed by the patentee to defend its exclusive right that truly matters. This view is exactly tantamount to the Actavis Court’s finding. Even a valid patent does not accord the patentee the right to exclude a potential competitor who did not infringe the patent at the expense of consumers by engaging in exclusionary practices of reverse payment settlements. Furthermore, the Commission rejected the scope of the patent test which resulted in the immunization of most reverse payment settlements from antitrust scrutiny. The Commission stated that even if commercial limitations on the generic firm’s commercial autonomy fell within the scope of the patent, they constituted a restriction of competition by object when they could not be otherwise justified, and did “not result from the parties’ [joint] assessment of the merits of the exclusive right itself [conferred by the patent] but in particular from a transfer of value overshadowing this assessment and inducing the generic [firm] not to pursue its independent efforts to enter the market.” Indeed, if there is no transfer of value as an inducement, and the settlement is purely based on each party’s assessment of its chance to prevail in the patent dispute, and the generic firm, as a rational economic operator, would not agree to the commercial limitations, but “instead act

480. Id.
481. Id. para. 1136.
482. Id. para. 1137.
483. Id.
485. Id.
486. Id. at 141.
487. See Case AT.39612—Perindopril (Servier), 2014 O.J. (C 4955), para. 1137.
independently in keeping with its own specific competitive incentives and resort to more pro-competitive solutions [such as] continued litigation, [and] acceptance of an early entry settlement.\textsuperscript{488} The Commission stressed that the reverse payment problematically manipulated the key terms of the patent dispute settlements which should have been purely based on the parties’ independent assessment of “(a) the validity of the patent, (b) whether there is an infringement of the patent by the generic [drug] and (c) the corresponding strength of each party’s litigation case.”\textsuperscript{489} The Commission recognized that an anticompetitive inducement to the generic firms might take the form of a side deal as a commercial arrangement behind the scene.\textsuperscript{490} It stated that where a side deal in relation to the patent dispute settlement was contingent upon the generic firm’s acceptance of the restrictive terms of the settlement, such a deal might serve as a de facto inducement to limit the generic firms’ ability to pursue commercial activities. When this is the case, scrupulous antitrust scrutiny may invite a comprehensive analysis of the link between the principal settlement, the side deal, and the commercial significance of that deal.\textsuperscript{491}

\textit{i. Key consideration factors for the object assessment.} The analyses of the Commission under the object-based approach in \textit{Servier} and \textit{Lundbeck} are nearly analogous to each other. The Commission made it clear that “the question of whether the agreement entailed actual [anticompetitive] effects [belonged] to the purely speculative sphere, and [was] not relevant for the purposes of competitive assessment (of restrictions by object).”\textsuperscript{492} The Commission noted that the antitrust focus should be on the question of whether the settlement removes a potential competitor and distorts the market structure resulting in market uncertainty as to commercial risks from competition and easing competitive pressure for the benefit of the brand manufacture.\textsuperscript{493} While the Commission found that the settlements between Servier and generic firms restricted competition by object, it took into account three key factors in identifying the anticompetitive nature of reverse payment settlements: (i) whether the parties were at least potential competitors, (ii) whether the generic firms committed to commercial limitations on independent efforts to enter the market, and (iii) whether those limitations are related to the transfer of value from the branded firm as a significant

\textsuperscript{488} Id. para. 1138.
\textsuperscript{489} Id. paras. 1138, 1188, 1371.
\textsuperscript{490} Id. para. 1190.
\textsuperscript{491} Id.
\textsuperscript{492} Id. para. 1144.
\textsuperscript{493} Id.
economic inducement. The Commission stated that “[a] reverse payment settlement may remove a potential competitor and distort the market structure, resulting in reduced risks from competition and the resulting market uncertainty, thus easing competitive pressure to the benefit of the [branded firm].” It found that payments from Servier to generic competitors were “the central and essential consideration for the conclusion of the [settlements]” in which the parties were economically better off at the expense of consumers. Indeed, reverse payments beyond the profits reasonably anticipated by the generic firms from market competition, but for the settlements, make both parties economically better off than they would be continuing “their own independent commercial course and rivalry,” so long as the above anticipated profits of the generic firms are lower than the loss in profits reasonably anticipated by the branded firm in case of generic entry. Hence, the Commission conceived the reverse payment as a significant economic inducement for the generic firms to forego their competitive incentives to launch their generic versions of the drug product on the market. One of the generic firms argued that reverse payment settlements were legitimate under the model linking the reverse payment with the parties’ assessment of the respective likely outcome of litigation, litigation costs, and anticipated loss/gain in profits. However, the Commission rejected this argument in light of the fact that this model did not discuss consumer welfare, but merely explained why both parties could be better off under the settlement than by continued litigation and subsequent market competition and, furthermore, linking the reverse payment to anticipated loss/gain in profits in the counterfactual scenario of competition simply suggested the anticompetitive nature of the settlement. The Commission stressed that payments to avoid the uncertainty of potential competition were not legitimate from an antitrust purpose. This view implies that the parties’ interests in avoiding the risk of competition do not work to offset the anticompetitive nature of the reverse payment. The Commission further noted that from a functional perspective the settlements effectively eliminated “the possibility of generic entry against the certainty of non-entry.” It viewed the reverse payment settlement at

494. Id. para. 1154.
495. Id. para. 1144.
497. Id. paras. 1146–1147.
498. Id. paras. 1374, 1480, 1626, 1999.
499. Id. para. 1209.
500. Id.
501. Id.
502. Id. para. 1374.
issue as being equivalent to a rent-sharing agreement or market-sharing agreement.503 Precisely speaking, four settlements with cash payments from Servier were regarded as rent-sharing agreements by which the interests of the counterparties to each settlement were aligned; in comparison, the other settlement, including an economic inducement for Servier to grant a solo license for the relevant patent in return for a low level of royalties at three percent of the generic firm’s sales value, was found akin to a market sharing agreement.504

ii. Analytical commonality between Servier and Actavis. Overall, it seems that both the Commission in Servier—in Lundbeck as well—and the Actavis Court particularly share two key standpoints. First, both of them deny a risk-aversion defense of the parties in antitrust scrutiny over payment for delay. This is because exclusion payments to avoid the risk of patent invalidity will result in the elimination of the risk of competition.505 Thus, the risk of patent invalidity is not irrelevant to, but associated with, the risk of competition. The settlements including payments for delay do nothing but harm consumers because they have genuine anti-competitive objectives and effects. These exclusion payment settlements eliminate the risk of competition borne by the patentee by foreclosing potential competitors from the relevant market and consequently strengthening the patentee’s monopoly. Hence, the risk of invalidity, whether small or large, would not justify exclusion payments in any event. This is simply because avoiding the risk of invalidity will lead to eliminating the risk of competition. The EC and the Actavis Court held that preventing even a small risk of competition constituted an antitrust violation.506 But the Actavis Court did not explain under what situation the risk-aversion defense is acceptable. One may present the hypothetical situation where the sufficiently risk-averse patentee tries to justify its large payment by showing that the patent dispute settlements between it and generic challengers guarantee earlier generic entry than would be expected from litigation and thereby introduce more competition for the benefit of consumers.507 Theoretically the risk-aversion defense in this situation sounds plausible given that those settlements do

503. Id. paras. 1373, 1479, 1625, 1763, 1998.
504. Id. paras. 1373, 1479, 1625, 1739, 1763, 1998.
506. Actavis, 570 U.S. at 156–57; see Edlin et al., supra note 134, at 17, 20 (noting that the elimination of the risk of competition occurs “if the agreed period of competition is smaller than what could be expected from the (in this case small) probability of the patentee losing the patent litigation.”).
507. Edlin et al., supra note 134, at 20.
not ease but facilitate competition even if they include reverse payments exceeding the patent’s prospective litigation costs. This situation may occur when the patentee wants to avoid facing the small risk of facing more competition that would occur when the patent is found invalid or not infringed against its expectations. Taking the example to the extreme, if the patentee had a 99 percent chance of winning litigation, and wanted to avoid the small risk of the patent being found invalid or not infringed, it would be willing to pay generic challengers an amount—in excess of the remaining litigation costs—and also grant a covenant of earlier access to the market. However, this hypothetical situation is unrealistic because it does not reflect rational decision-making of the parties. In other words, this situation does not represent the parties’ market-based business judgment about the perceived merits of the patent case.508 This anomalous situation would not occur in the real world because a patentee sure to win litigation would not make payments exceeding reasonably anticipated litigation costs. Even if the patentee would do so, it would expect to receive a return of value equivalent to the payments. Nevertheless, the above hypothetical case, which is intended to show that “even a small risk of invalidity [may] justif[y] a large payment,” merely identifies the asymmetry of a quid pro quo in that large payments from the patentee, together with a guarantee of earlier generic entry, do not correspond to what the patentee’s benefit from averting the small risk of invalidity.509

Second, both the Actavis Court and the Commission took the consumer welfare approach in examining the legality of reverse payment settlements.510 In other words, they structured their antitrust analysis by answering the cardinal question of whether the settlements at issue create, maintain, or strengthen the patentee’s monopoly to the detriment of consumers. Actavis, Lundbeck, and Servier hold that the anticompetitive nature and effect of reverse payment settlements is attributed to their adverse impacts on competition in terms of consumer welfare, which contrasts with total welfare, including producer welfare as well as consumer welfare.511 By contrast, the total welfare approach examines

510. See Case AT.39612—Perindopril (Servier), Comm’n Decision, 2014 O.J. (C 4955), para. 1209 (EC) (stressing the significance of consumer welfare discussion in antitrust scrutiny); Actavis, 570 U.S. at 152–57 (stating that pay-for-delay settlements make the patentee and the generic challenger better off whereas they make consumers worse off). Likewise, in his dissenting opinion, Chief Justice Roberts stated that “[t]he point of antitrust law is to encourage competitive markets to promote consumer welfare.” Id. at 161 (Roberts, C.J., dissenting).
511. See Actavis, 570 U.S. at 136; Case C-591/16, Lundbeck v. Comm’n, ECLI:EU:C:2021:243 (Mar. 25, 2021); Case AT.39612—Perindopril (Servier), 2014 O.J. (C 4955).
all welfare effects in the market. Thus, there exists a bright line between the consumer welfare approach and the total welfare approach. Where reverse payment settlements harm consumers by increasing drug prices but benefit producers by lowering manufacturing costs, the consumer welfare approach may identify consumer loss itself as the degree of the anticompetitive effect of settlements while the total welfare approach may generate the net competitive effect by having consumer loss offset by producer profits.

c. Effect-based approach under Article 101. The Commission examined the likely anticompetitive effects of the settlements at issue under the effect-based approach for the sake of completeness even though it concluded they clearly fell under the purview of the by-object restriction of competition within the meaning of Article 101 of the TFEU. The Guidelines on the Application of Article 81(3) of the Treaty provide that “[n]egative effects on competition within the relevant market are likely to occur when the parties individually or jointly have or obtain some degree of market power and the agreement contributes to the creation, maintenance or strengthening of that market power.” According to the Guidelines on the Applicability of Article 101 of the Treaty on the Functioning of the European Union to Horizontal Co-operation Agreements (hereinafter referred to as Horizontal Guidelines) the agreement has restrictive effects on competition when it “has, or is likely to have, an appreciable adverse impact on at least one of the parameters of competition on the market, such as price, output, product quality, product variety or innovation.” Restrictive effects arise from “obligations contained in the agreement which regulate the market conduct of at least one of the parties or by influencing the market conduct of at least one of the parties... by causing a change in its incentives.” The Horizontal Guidelines provide that the assessment of restrictive effects on competition depends on:

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512. *Actavis*, 570 U.S. at 152–54 (stating that the reverse payment settlement makes the parties better off by producing monopoly returns for the branded firm to be shared with the generic, which otherwise would flow to consumers but for the settlement).

513. *Hovenkamp*, supra note 211, at 7; Edlin et al., *supra* note 134, at 17.


516. *Id.*
the nature and content of the agreement, the extent to which the parties individually or jointly have or obtain some degree of market power, and the extent to which the agreement contributes to the creation, maintenance or strengthening of that market power or allows the parties to exploit such market power.517

Taking a stance in line with the Horizontal Guidelines, the Commission specifically examined four factors, in turn, for the effect analysis: (1) Servier’s position in the relevant market, (2) whether the generic firms were potential competitors in the relevant market, (3) the content of the settlements and significant inducement that led the generic firm to accept its contractual limitations and, (4) the competitive behavior that the generic firms would have been likely to engage in, absent the settlements.518 The Commission noted that what matters is not if there is a certain degree of actual, effective competition on the market, but if the settlements foreclose potential competition.519 Thus, the Commission stated that the existence of actual competition could not justify restriction of potential competition.520

In regards to the market position factor in particular, the Commission identified Servier’s market position by assessing its market power.521 As stated below, the Commission diverted market power assessed for the purpose of the identification of Servier’s market dominance under Article 102 to the effect analysis under Article 101 pursuant to the Horizontal Guidelines.522 In the framework of finding Servier’s market dominance under Article 102, the Commission established that Servier held enough market power in both the relevant product and technology markets that it could charge the prices substantially above the competitive-level prices approximated by post-generic entry prices.523 The Commission further found that reverse payment settlements strengthened that power to the extent that Servier could enjoy supracOMPetitive economic rents.524 Economic rents refer to “the difference between the actual returns from an activity and the returns necessary to attract recourses to conduct

517. Id. para. 28.
518. See Case AT.39612—Perindopril (Servier), Comm’n Decision, 2014 O.J. (C 4955), paras. 1224–1227 (EC).
519. Id. para. 1227.
520. See id. paras. 1224–1227.
521. Guidelines on Article 101, supra note 515, para. 42.
522. Id. (providing that the degree of market power required for the finding of anticompetitive effects under Article 101 is less than the degree of market power for proof of the abuse of market dominant position under Article 102).
523. Case AT.39612—Perindopril (Servier), 2014 O.J. (C 4955), para. 1242.
524. Id. paras. 1242–1243.
that activity."\textsuperscript{525} Thus, economic rents are equivalent to monopoly profits.\textsuperscript{526} In the Commission’s view, Servier’s substantial economic rents resulted from market power.\textsuperscript{527} In other words, the Commission considered economic rents as functioning to confirm market dominance, i.e., market power.\textsuperscript{528}

The Commission stated that the anticompetitive effects of the settlements in question could be inferred directly from conduct of the parties to the settlements, i.e., payments for delay.\textsuperscript{529} It found that the settlements reduced competition and led to a price hike for the drug, thereby resulting in higher customer spending on the drug than in earlier generic entry.\textsuperscript{530} Notably, the Commission’s approach in Servier was similar to the rule of reason taken by the Actavis Court. Thus, the Commission analyzed the effects of reverse payment settlements by examining the market power under the traditional market definition-market share paradigm and assessing the competitive effects of Servier’s conduct of large payments.\textsuperscript{531} This approach accords with the Guidelines on Article 81(3), which allow the direct inference of anticompetitive effects from the joint conduct at issue when such conduct itself manifests consumer harms, for example, anticompetitive ways to charge substantially higher prices and reduce consumer choice.\textsuperscript{532} However, from a procedural perspective Actavis is still distinguished from Servier in that the Actavis Court did not rigorously separate the market power analysis and the effect analysis; but rather, opted for a de facto consolidated approach by focusing on defendant’s conduct.\textsuperscript{533} Thus, the Court found that a large unexplained payment works as proof of power and effects.\textsuperscript{534} This approach allowed the Court to avoid complex processes of analyzing market power and effect separately.

d. Market dominance analysis under Article 102. The meticulous assessment of market power in Servier was carried out in the course of finding market

\begin{footnotesave}
\textsuperscript{525} Id. para. 2579.
\textsuperscript{526} Id.
\textsuperscript{527} Id.
\textsuperscript{528} Id.
\textsuperscript{529} Id. para. 1243.
\textsuperscript{530} Id.
\textsuperscript{531} Id. paras. 1224–1243.
\textsuperscript{532} Guidelines on Article 81(3), supra note 347, para. 27; \textit{see also} Case AT.39612—Perindopril (Servier), 2014 O.J. (C 4955), para. 1128 (noting that analyzing anticompetitive effects of the settlements on competition normally requires defining the relevant market, however those effects can be inferred directly from the particular conduct at issue).
\textsuperscript{534} Id.
\end{footnotesave}
dominance under Article 102. Article 102 prohibits the abuse of market dominance and thus is comparable to Section 2 of the U.S. Sherman Act which forbids an act to monopolize, an attempt to monopolize, or a conspiracy to monopolize.535 The determination of whether a firm abuses its dominant position within the meaning of Article 102 generally requires a three-step analysis. The first step is to assess whether a firm is in a dominant position; the second step is to determine whether the dominant firm engages in exclusionary practices and impairs effective competition by foreclosing its competitors in an anticompetitive way, thus having an adverse effect on consumer welfare; and the third step is to examine whether the firm’s abusive exclusionary conduct is justified on the grounds that it is objectively necessary or that it produces substantial efficiencies which outweigh any anticompetitive effects on consumers.536 In general, assessing dominance is treated as a question of market power of the firm.537 The guidance for the Commission’s enforcement priorities in applying former Article 82 of the Treaty Establishing the European Community (currently, Article 102 of the Treaty of the Functioning of the European Union, hereinafter Article 102 Enforcement Priorities Guidance) to abusive exclusionary conduct by dominant undertakings defines the term of dominance as meaning “a position of economic strength enjoyed by an undertaking, which enables it to prevent effective competition being maintained on a relevant market, by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of consumers.”538 In this analytical framework the Commission defined the boundaries of the relevant market and subsequently assessed Servier’s market power.539

After demarcating the relevant market, the Commission provided an in-depth analysis of the dominance assessment. It noted that a dominant firm may have “the ability to eliminate or seriously weaken existing competition or create barriers to entry for potential competitors, [but] the existence of a dominant position does not however require the [firm] enjoying it to have eliminated all possibility of competition.”540 Thus, the mere fact that the firm is in a dominant position does

535. TFEU, supra note 346, para. 1.
537. Id. para. 9.
538. Id. para. 10.
540. Id. para. 2552.
not imply that there is no competitive constraint facing it. In other words, it is the abuse of a dominant position, not holding the position, that is prohibited under Article 101. The Commission provided several factors to take into account in assessing Servier’s market power: (a) Servier’s position in the relevant market, (b) barriers to entry by potential competitors, (c) economic rents enjoyed by Servier, and (d) countervailing buying power, that are competitive constraints imposed by the bargaining strength of Servier’s customers. These consideration factors are also enumerated in the Article 102 Enforcement Priorities Guidance.

First, the Commission calculated Servier’s market share to identify its market position and found that it had high market shares in the relevant product market, which consisted of only the drug Servier enjoyed exclusivity over for most of the investigation period. Thus, the Commission derived such high market shares from Servier’s exclusivity over that product.

Second, the Commission found that Servier’s patents constituted significant barriers to generic entry. Servier could enjoy absolute protection afforded by the compound patent until its expiration and obtain limited protection with other process patents including even so-called paper patents and patents without an inventive step. The Commission found these barriers strengthened Servier’s market power because those patents incurred significant costs for generic competitors to bear in order to seek alternative processes and exposed them to the threat of infringement litigation with Servier. The Commission viewed Servier’s dominant position derived from market power as “inherent in the system where

541. Id.
542. Id. para. 2577.
543. Id. paras. 2553–2554.
544. See Guidance on Article 82, supra note 536, para. 12 (illustrating three factors for the assessment of dominance: “[a] constraints imposed by the existing supplies from, and the position on the market of, actual competitors (the market position of the dominant undertaking and its competitors), [(b)] constraints imposed by the credible threat of future expansion by actual competitors or entry by potential competitors (expansion and entry), [(c)] constraints imposed by the bargaining strength of the undertaking’s customers (countervailing buyer power).”).
545. Case AT.39612—Perindopril (Servier), 2014 O.J. (C 4955), para. 2568.
546. Id. para. 1241.
547. Id. paras. 2572–2577.
548. Id. para. 2572.
549. Id. para. 2574.
innovation [was] rewarded by exclusivity that intellectual property rights confer[red] on the author of the innovation."

Third, the Commission established the size of economic rents enjoyed by Servier during the term of the settlement. Economic rents are derived from market power and thus, represent monopoly profits. Hence, economic rents confirm the economic strength enjoyed by Servier. The Commission quantified economic rents by comparing the product prices before and after the patent expiry and multiplying the gap in those prices with quantities sold by Servier during the period of investigation. It viewed the post-generic entry price as representing "a conservative estimate of the effective competition price level." Servier argued that the Commission erred in assessing its economic rents by "compar[ing] the price of a product under patent protection with the price of the same product after the elapse of patent protection." Servier contend that the Commission failed to take into account the astronomical costs for research and development of the pioneer drug which could be rewarded by monopoly profits under the settlement. However, the Commission rejected this argument stating that innovation and development costs could not disturb the inference of market power from the ownership of an intellectual property right, and therefore, economic rents as assessed from the comparison between pre- and post-generic entry prices properly suggested market dominance. Furthermore, the Commission considered the costs incurred for innovating and developing new drugs simply sunken costs which were likely not to be always recouped. Therefore, it found unacceptable Servier’s argument that it had to redeem those invested (but sunken) costs to sustain its business in the long run.

Fourth, competitive constraints may result from actual or potential competitors or the bargaining power of the dominant firm’s customers. Thus, the buying power of customers offsets the market power of the dominant firm. The Article 102 Enforcement Priorities Guidance provides that countervailing buying

550. Id. para. 2577.
551. See id. para. 2598.
552. See id. para. 2579.
553. Id. para. 2579.
554. Id. para. 2580.
555. Id.
556. Id. para. 2556.
557. Id. paras. 2556, 2584.
558. Id. para. 2584.
559. Id. para. 2585.
560. Id.
power may arise from “the customers’ size or their commercial significance for the dominant [firm], and their ability to switch quickly to competing suppliers, to promote new entry or to vertically integrate, and to credibly threaten to do so.”

The Commission found that Servier remained free of countervailing buying power, which would impose a downward pressure on its substantial economic rents but could behave—to an appreciable extent—indepedently vis-à-vis its customers.

Following the foregoing analysis, the Commission concluded that Servier was in a dominant position in the relevant market within the meaning of Article 102.

Servier, as in line with Lundbeck, reveals progress on developing and fine-tuning the current antitrust rules to regulate reverse payment settlements. It offers further elaboration and clarification of those rules by expanding the scope and depth of discussion beyond the jurisprudential limit of the Actavis rationale. Thus, the jurisprudential ambiguity arising from Actavis seems addressed by the set of rules as added and clarified by joint and complementary reading of Servier and Lundbeck.

IV. SYNTHESIZING RULES TO BRIDGE THE GAP

Considering both landmark decisions in the United States and the European Union, what distinguishes them from one another is the discrepancy of analytical approaches formulated by the courts. The common governing rule in Lundbeck and Servier is the notion of restriction by object which is generally compared to a per se or quick look rule in U.S. competition law. By contrast, the Actavis approach is based exclusively on the rule of reason. Despite factual discrepancies, competition law in the United States and the European Union, from a holistic perspective, seems to have followed a nearly convergent path in antitrust regulation of reverse payment settlements in the pharmaceutical industry. In Lundbeck, Servier, and Paroxetine, compound and original process patents already

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561. See Guidance on Article 82, supra note 536, para. 18.
562. See Case AT.39612—Perindopril (Servier), 2014 O.J. (C 4955), paras. 1241, 2582, 2592.
563. Id. para. 2593.
566. Actavis, 570 U.S. at 136; Case AT.39612—Perindopril (Servier), 2014 O.J. (C 4955); Lundbeck, ECLI:EU:C:2021:243.
567. Lundbeck, ECLI:EU:C:2021:243; Case AT.39612—Perindopril (Servier), 2014 O.J. (C 4955).
568. Actavis, 570 U.S. at 136.
expired before the parties entered into reverse payment settlements, while in *Actavis*, the term of the relevant patent was still valid until far after the settlement was terminated.569

A. The Strength of the Patent

Furthermore, one related factor for legal assessment in these three EU cases were that the patents at stake were relatively weak. The courts did not accept claims based on the presumptive validity of patents at issue.570 The branded firm’s claim—that it is incentivized to enter into reverse payment settlements to prevent market entry—may not be based on the original compound patent, but on secondary patents (on the manufacturing process) obtained at a subsequent stage.571 As long as the compound itself is no longer protected by a patent, a generic firm is, in principle, able to manufacture the drug. Thus, process patents may not allow the branded firm to prevent market entry.572 “If a generic [firm] develops an alternative, non-infringing process, it would be in a position to lawfully market the drug.”573 Accordingly, in a settlement concluded where a non-infringing process is available, a genuine intellectual property dispute may not exist in the sense that the branded firm would not be in a position to prevent entry even if its process patent was deemed valid.574 The relatively weak nature of process patents shapes the legal assessment.575 Statistical analysis shows that process patents in general are more likely to be deemed invalid than product or compound patents.576 The Commission’s Sector Inquiry Report shows that generic manufacturers prevail in over two-thirds of disputes involving process or secondary patents, whereas branded manufacturers prevail in over one-half of disputes concerning product patents.577 These statistics suggest that a branded manufacturer may have an strong

569. AT.39612—Perindopril (Servier), 2014 O.J. (C 4955); Lundbeck, ECLI:EU:C:2021:243; Case C-307/18, Generics (UK) Ltd. v. Competition & Mkts. Auth., ECLI:EU:C:2020:52 (Jan. 30, 2020); Actavis, 570 U.S. 136.

570. See Case AT.39612—Perindopril (Servier), 2014 O.J. (C 4955); Lundbeck, ECLI:EU:C:2021:243; Generics (UK), ECLI:EU:C:2020:52.


572. Colomo, supra note 420, at 603.

573. Id.

574. Id.

575. Id.


577. Id.
incentive to settle the patent dispute—even by paying generic manufacturers alleged to have infringed.578

B. The Size of the Payment

Lundbeck and Servier, in line with Actavis, connote that the size of the payment adds to the peculiarity of reverse payment settlements.579 Competition authorities raised antitrust concerns, not only due to the reverse nature of the payment, but also because the payment sometimes amounted to far more than the litigation costs.580 The size of exclusion payment coupled with the likelihood that the patent will be found invalid generally indicates that a pay-for-delay settlement formed a profit-sharing collusion.581 “[T]he objective purpose of the payment would not be to settle the dispute but to share monopoly profits between [branded] and generic” manufacturers in competition.582 Unlike traditional settlements, which reflect a certain degree of adversarial relationship between the parties, the pay-for-delay settlements make both parties better off by allowing the sharing of the full monopoly overcharge in a way to reciprocally give each party an expected value greater than the probable value of the patent at bar.583 An alternative to exclusion payments that could make the settlement lawful would be an agreement of delayed entry without any value transfer from the branded to generic firm.584 A settlement of this kind does not align the incentives of both parties but still reflects adversity as their interests would contrast with each other in terms of the length of delay.585 Rather, the likelihood of the settlement to delay entry would depend upon the realistic joint assessment of the strength of the patent, in other words, the likely outcome of litigation.586

This notion adds an important caveat that needs attention. The validity of the patent dictates the size of the settlement, but does not drive the likelihood of a pay-for-delay settlement.587 The likelihood of the settlement depends on the generic’s

578. Id.
579. Colomo, supra note 420, at 603.
580. Id.
581. Id.
582. Id.
583. Hovenkamp, supra note 211, at 26–27.
584. Hovenkamp et al., supra note 42, at 1762.
585. Id.
586. Id.

assessment of the anticipated post-entry profits relative to the value of the settlement.\(^{588}\) A generic manufacturer who believes a patent is 100 percent likely to be held invalid might still find it more valuable to share the monopoly profits with the patentee for the duration of the settlement rather than entering the market to compete.\(^{589}\) Likewise, a patentee, sure that a patent is valid, might be willing to pay “little more than a nuisance fee to avoid litigation costs.”\(^{590}\) Thus, the size of the exclusion payment for the generic is likely to equal or exceed the profits it could have anticipated to obtain when entering the market. That said, the analysis of whether the net gain via the value transfers is sufficiently significant to incentivize the generic to refrain from entering the market and not to compete on the merits with the branded should be addressed on a case-by-case basis.\(^{591}\) Beyond the vague \textit{Actavis} inference, \textit{Lundbeck} notably elucidates the size of anticompetitive reverse payments and solves the controversy over it.\(^{592}\) Thus, the reverse payment was found to broadly correspond to the profits that the generic manufacturers had expected to make if they had entered the market or to the damages that could have been paid to them if they had prevailed in the patent proceedings against Lundbeck.\(^{593}\) In other words, it is not required that the net gain should necessarily be greater than the profits that the generic manufacturers would have made if they had been successful in the litigation.\(^{594}\) This flexibility offers additional clarity to the definition of the exclusion payment and fills a gap that remained open since \textit{Actavis}.

\textbf{C. The Genuineness of the Patent Dispute}

One of the key findings inferred from transatlantic jurisprudential comparison is that antitrust analysis of pay-for-delay settlements in legal and economic contexts calls for the examination of whether the patent dispute

\begin{flushright}
588. Hovenkamp, \textit{supra} note 211, at 12.
589. \textit{Id.}
590. \textit{Id.} at 12–13; Crane, \textit{supra} note 55, at 704 (noting that “costs of continuing to litigate may explain patentees’ eagerness to settle infringement lawsuits for payments to the defendants in excess of their expected out-of-pocket litigation costs, even when the patentees have a strong ex ante likelihood of ultimately succeeding in the lawsuit.”).
592. See \textit{id.}.
593. \textit{Id.} para. 135.
594. \textit{Id.} para. 115.
\end{flushright}
underlying the settlement is genuine. 595 This question needs to be answered on a case-by-case basis “[s]ince one cannot presume that, absent the settlement, the generic would have infringed the patent” at issue.596 Two scenarios can be considered.

The first scenario presupposes that the patent dispute is false, and therefore, exceeds the scope of the intellectual property right. The uncertainty in whether there is an actual dispute about the status of the patent at issue may make it difficult to determine whether the settlement is concluded between (actual or potential) competitors or between non-competitors.597 If the parties doubtlessly have the ability and incentive to operate in the relevant market, the dispute may not be considered genuine in light of the fact that the dispute does not relate to the alleged infringement of a patent.598 In such circumstances, one would reasonably conclude that the settlement not to compete has anticompetitive purposes without addressing a genuine patent dispute.599 Identifying the precise purpose of the settlement requires further analysis scrutinizing other factors pertaining to the economic and legal context.600 The predominant antitrust jurisprudence in both the United States and the European Union, as established by Actavis and Lundbeck, suggests that the size of the reverse payment is a strong indicator of the anticompetitive effect and market power.601

The second scenario, by contrast, presupposes the dispute is genuine and falls within the scope of the intellectual property right.602 In this case, a genuine patent dispute itself substantiates that the dispute would remain within the scope of the patent right.603 The patentee successful in litigation would be in a position to prevent entry.604 This would create a probability that the parties would not be, whether actual or potential, competitors. Thus, a settlement addressing a genuine patent dispute may or may not restrict competition, depending on the outcome of litigation and on the validity of the patent. If the dispute is genuinely related to the

595. Colomo, supra note 420, at 603.
596. Id.
597. Id. at 598.
598. Id. at 601.
599. Id. at 602 (noting “any restrictions of competition [are] attributable to the agreement, the scope of which [is] broader than the intellectual property right.”).
600. Id. at 594.
601. See id. at 605.
602. See id. at 602.
603. See id.
604. See id.
validity or the infringement of a patent, the precise purpose of an agreement, it is least likely to settle the dispute out of court.605 As such, the genuineness of the dispute might exempt the settlement from antitrust accusation of restriction of competition by object. However, the settlement of such nature might still be condemned for restriction of competition by effect. Therefore, the authority may need to show not only that the practice at issue is restrictive by object but also that it has, or is likely to have, restrictive effects on competition.606 In principle, the EU’s competition law does not question or negate the existence of the intellectual property rights. Accordingly, the effect analysis cannot be based on whether the patent is valid and infringed but based on circumstantial evidence showing that it is more likely than not that there would have been competition absent the practice at issue.607

Table 2. Four Scenarios Regarding the Genuineness of the Patent Dispute

<table>
<thead>
<tr>
<th>False patent dispute</th>
<th>Primary patent</th>
<th>Generic entry is delayed beyond the expiration of primary patent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary patent</td>
<td>Primary patent</td>
<td>Primary patent has expired but generic entry is possible through other unpatented processes</td>
</tr>
<tr>
<td>Genuine patent dispute</td>
<td>Primary patent</td>
<td>Primary patent has not expired</td>
</tr>
<tr>
<td>Secondary patent</td>
<td>Generic entry is only possible through the patented process</td>
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Lundbeck concerns the patent dispute under the first scenario. One can think of two probable cases. The first case is that the settlement prevents generic entry beyond the patent expiration. The second case is that the patent invoked by the patentee would not prevent generic entry even when the patent is held to be valid and infringed. This particular case arises when the primary patent has expired and the patented process is not the only way by which the generic drug can be

605. Id. at 602 (referring to the European Commission’s Guidelines on Technology Transfer Agreements stating that “the authority emphas[i]zed the pro-competitive gains that come with [intellectual property] settlements, including the efficient use of courts’ and authorities’ resources, and thus give rise to gains for society as a whole.”); Guidelines on Article 101, supra note 515, para. 235.
606. Colomo, supra note 420, at 602.
607. Id.
manufactured.\textsuperscript{608} By settling with the generics for delayed entry, the patentee would insulate itself from competition and obtain a degree of protection that otherwise could not be obtained through the patent system.\textsuperscript{609} \textit{Lundbeck} by and large exemplifies this case.\textsuperscript{610} In \textit{Lundbeck}, the Commission stated that the generics were able to enter the market using a manufacturing method other than allegedly protected by the process patent at issue.\textsuperscript{611} Lundbeck claimed that the generics would not have entered even if alternative processes to manufacture had been available. To establish the absence of potential competition, Lundbeck needed to show either that the generics were unable to manufacture the drug due to the strength of the process patent or that the generics did not intend to enter the market—even using other processes available.\textsuperscript{612} The ECJ denied these arguments on the ground that it is sufficient to show that potential competitors would “more likely than not” enter within a short period of time, without necessarily establishing that generic entry would have happened in the absence of the settlement.\textsuperscript{613}

As above noted, a pay-for-delay settlement can also concern a genuine patent dispute under the second scenario. The dispute occurs \textit{either} where the primary patent has not expired at the time of the settlement or where the generics would only be able to manufacture the drug using a patented process. In either case, generic entry is lawful only where the relevant patents are found invalid or not infringed.\textsuperscript{614} A settlement the parties enter into is facially regarded as “an alternative mechanism to bring an actual or potential dispute to an end” and therefore the settlement in and of itself is unlikely to be declared as precisely purporting to restrict competition.\textsuperscript{615} \textit{Paroxetine}, also referred to as \textit{Generics},

\begin{thebibliography}{9}
\bibitem{608} Id. at 604.
\bibitem{609} Id.
\bibitem{610} See id.
\bibitem{611} Case AT.39226—Lundbeck, Comm’n Decision, 2013 O.J. (C 3803) 211, paras. 634–646 (EC) (“Lundbeck itself confirmed to the Commission that its process patents were not capable of blocking all possible routes to the market: ‘. . . generic entrants could have produced citalopram by using the process described in Lundbeck’s original compound patent filed in 1977, albeit with a different and potentially less efficient method of purification, or they could have invested to invent an entirely new process.’”) (further stating “Lundbeck also explained to the Commission that ‘In the 2002-2004 timeframe, there were several processes available to produce citalopram. Instead of using one of the several processes available, generics freely chose to use the process described in the Crystallization patent because it was more efficient than the other processes.’”).
\bibitem{612} Id. para. 634.
\bibitem{613} Colomo, \textit{supra} note 420, at 604.
\bibitem{614} Id.
\bibitem{615} Id.
\end{thebibliography}
provides useful insights into a patent dispute in this context. Paroxetine is the first case where the ECJ ruled on the legality of patent dispute settlements in the pay-for-delay context. However, it is noteworthy that Paroxetine reached the ECJ by virtue of a request for a preliminary ruling from the UK Competition Appeal Tribunal (CAT), which sought the interpretation of European Union law. Therefore, Paroxetine differs in essence from Lundbeck and Servier in terms of procedural history. The reference for a preliminary ruling involved an appeal by the branded manufacturer GlaxoSmithKline (GSK) and five generic manufacturers from a 2016 decision of the UK Competition and Markets Authority (CMA), that GSK and generics had part in unlawful agreements, concerted practices, and that GSK had abused a dominant position. GSK was the holder of a patent for the active pharmaceutical ingredient of the anti-depressant medicine Paroxetine, specifically a primary (or principal) patent, and secondary patents protecting some processes for the manufacture of that ingredient. After the expiration of the primary patent in 1999, generic manufacturers contemplated entering the market by launching generic versions of Paroxetine. GSK brought various actions against those manufacturers for infringement of secondary patents, and they challenged the validity of one of those patents. GSK settled patent disputes with generics by paying them to stay out of the market. The CMA found that these pay-for-delay settlements infringed Article 101 of the TFEU and the equivalent prohibition in Chapter I of the Competition Act 1998. The CMA also found that

617. Id. para. 2.
620. Id. para. 10.
621. Id. paras. 13–14. In these patent disputes, generic manufacturers challenged the validity of the Anhydrate patent, which was issued in 1997 and expired in 2016. Subsequently, GSK concluded two pay-for-delay settlement agreements with those manufacturers. One agreement was created with Generics joined by Merck in 2002, and expired in 2004, and the other was done with companies in the Alpharma group—Actavis UK, Xellia Pharmaceuticals and Alpharma—in 2002, and expired in 2004. Id. paras 13–15.
622. Id.
623. Id. para. 15; Case CE-9531/11, Paroxetine, Decision of the Competition & Mkts. Auth., para. 1.14 (Feb. 12, 2016), https://assets.publishing.service.gov.uk/media/57aaf65be5274a0f6c000054/ce9531-11-paroxetine-decision_.pdf [https://perma.cc/S6BA-XRCT].
GSK held a dominant position in the market for Paroxetine, and had abused that position, contrary to the prohibition in Chapter II of the Competition Act 1998, by entering into such settlements.\(^{624}\) GSK and the generics appealed the CMA’s decision to the CAT in 2016, which in turn rendered a preliminary judgment where it decided to stay the proceedings and refer a number of substantive questions to the ECJ.\(^{625}\) These questions concerned notions of potential competition, restrictions on competition by object and by effect, and abuse of market dominance and market definition.\(^{626}\)

What distinguishes *Paroxetine* from *Lundbeck* is that the CMA did not appear to explicitly claim or adduce evidence showing generic manufacturers were able to enter the market by processes other than those protected by a secondary patent at issue.\(^{627}\) This observation along with a fact that GSK obtained an interim injunction preventing generics from entering the market suggests by circumstantial evidence that the settlements at issue concerned a genuine patent dispute.\(^{628}\) At the extreme, one might argue that the existence of a genuine dispute, in and of itself, establishes a prima facie case that the settlements do not fall within the scope of prohibited agreements or concerted practices.\(^{629}\) Such a view highlights that antitrust analysis can only be based on the assumption that the patent is valid under the principle that EU law does not question the existence of intellectual property rights.\(^{630}\) This is in direct contrast with the established case law in *Actavis*, *Lundbeck*, and *Paroxetine*, according to which patent-related justifications are

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624. *Paroxetine*, supra note 623, paras. 1.20, 8.36; *Generics (UK)*, ECLI:EU:C:2020:52, para. 15.


626. *Generics (UK)*, ECLI:EU:C:2020:52, paras. 18–21; see also *Generics (UK)*, supra note 625.

627. Colomo, supra note 420, at 605; *Paroxetine*, supra note 623, annex D § B.

628. *See Generics (UK)*, ECLI:EU:C:2020:52, paras. 53, 98, 102 (stating that the granting of an interim injunction cannot prejudice the merits of an infringement action or shed any light on the outcome of a patent dispute, and therefore has no relevance to the determination of the existence of restrictions of competition by object).

629. Colomo, supra note 420, at 605 (“Absent factual evidence establishing that the generic producer was able to enter the market without relying on the patented processes, it seems in principle difficult to conclude that the CMA had shown, to the requisite legal standard, that the said agreements were caught, by their very nature, by Article 101(1) TFEU.”).

630. *Id.* at 599.
basically isolated from antitrust questions.\footnote{Fed. Trade Comm’n v. Actavis, Inc., 570 U.S. 136, 138 (2013); Case C-591/16, Lundbeck v. Comm’n, ECLI:EU:C:2021:243, paras. 58–59 (Mar. 25, 2021); \textit{Paroxetine}, supra note 623, para. D.19.} A view of this kind, rationalizing a pay-for-delay settlement insofar as it relates to a genuine dispute, simplifies a dynamic and variety of landscapes of the economic and legal context in which the settlement takes place and does not fully capture the complexity of the settlement.\footnote{Colomo, supra note 420, at 605 (justifying unexplained large exclusion payment by noting that “from an economic perspective, there are grounds to conclude that a settlement can provide for a reverse payment, even a large one, for pro-competitive reasons . . . [and] that litigation is inherently uncertain and . . . an originator may be particularly risk averse when the profitability of one of its blockbuster drugs is at stake. In such an economic and legal context, it does not come across as implausible that the party that stands to lose the most from litigation offers a payment to the other party.”); \textit{see} Cotter, supra note 61, at 1808–14 (noting a similar position arguing that it is generally rational for pharmaceutical patentees to agree to pay generic competitors).}

The ECJ in \textit{Paroxetine} lucidly noted that the genuineness of the patent dispute does not preclude the existence of competition between the patentee and the generics seeking market entry, but rather constitutes evidence showing the existence of a potential competitive relationship.\footnote{Id. para. 76.} The ECJ nonetheless noted that the existence of a genuine patent dispute precludes the agreements at issue from being irrefutably characterized as “agreements bringing to an end entirely fictitious disputes, or as designed with the sole aim of disguising a market-sharing agreement or a market-exclusion agreement.”\footnote{Id. para. 102.} However, this does not mean that the genuine dispute completely excludes the practices in question from the characterization of by object restriction. As the Court clarifies, the genuineness of the patent dispute has limitations when used to assess the existence of a restriction of competition by object.\footnote{Id. para. 77.} Antitrust condemnation further requires the competition authority or factfinder to assess whether the agreement at issue may be equivalent to market-sharing agreements or market-exclusion agreements that harm competition.\footnote{Case C-591/16, Lundbeck v. Comm’n, ECLI:EU:C:2020:428, para. 4 (June 4, 2020).} The ECJ, in \textit{Lundbeck}, likewise found that the settlements at issue purported only to delay entry, but not to settle patent disputes, which makes the genuineness of patent at issue questionable.\footnote{Generics (UK), ECLI:EU:C:2020:52, para. 52.}
D. The Rigidness of the Approach

In *Lundbeck*, the general court endorsed a broader interpretation of the concept of restriction of competition by object and showed a lack of receptiveness to the specificities of the pharmaceutical industry, the dynamics of the interplay between competition law and intellectual property law, and the imperfect patent enforcement system. By contrast, the ECJ in *Lundbeck* and *Paroxetine* contemplates such a concept as being strictly interpreted, but allows enough flexibility to recognize and take into account as a factor the peculiarity of the relationship between competition law and intellectual property law. Thus, the ECJ adopts a prudent approach in interpreting and applying the restriction of competition by object and attempts not to excessively circumscribe the scope of the restriction.

Notably, pay-for-delay analysis in the EU competition law may invite either a by-object approach or a by-effect approach, which is roughly equivalent to the rule of reason in U.S. jurisprudence. The object and the effect are generally considered on an alternate basis depending on whether an agreement at issue has the object of restricting competition, the existence of which invites a by-object approach and obviates the need to assess the effect of the agreement on competition. Nevertheless, the competition authority or antitrust plaintiff

638. QC & Diaz, *supra* note 454, 28 (“The General Court’s confirmation that potential competition may exist regardless of regulatory barriers to entry, in particular intellectual property rights, and that patent settlements may restrict competition by object regardless of whether they are within the scope of the patent at issue and of the counterfactual deviates from well-established principles.”).

639. Case C-307/18, Generics (UK) Ltd v. Competition & Mkts. Auth., ECLI:EU:C:2020:52, para. 67 (Jan. 30, 2020). (“It is clear from the Court’s case-law that the concept of restriction of competition ‘by object’ must be interpreted strictly and can be applied only to some concerted practices between undertakings which reveal, in themselves and having regard to the content of their provisions, their objectives, and the economic and legal context of which they form part, a sufficient degree of harm to competition for the view to be taken that it is not necessary to assess their effects, since some forms of coordination between undertakings can be regarded, by their very nature, as being harmful to the proper functioning of normal competition.”); Case C-591/16, Lundbeck v. Comm’n, ECLI:EU:C:2021:243, para. 112 (Mar. 25, 2021)

640. *Generics (UK)*, ECLI:EU:C:2020:52, para. 99 (“If it were accepted that such factors made it possible to exclude from characterisation as a ‘restriction by object’ a practice capable of displaying, in itself, a sufficient degree of harm to competition, that would be liable excessively to circumscribe the scope of that concept, even if it is to be interpreted strictly.”).

641. *Id.* para. 19.

642. *Id.* para. 64.
successful in showing such an anticompetitive object can still implicitly assess the
effect of restricting competition, which requires more complex analysis, to make a
stronger and more viable case demonstrating the illegality of the practice at
issue.643

E. Interaction of Competition Law and Intellectual Property Law

Competition law and intellectual property law may interact with each other
on the interpretation and application of rules to the issues on the border or
involving a mix of consideration factors. However, these two laws are not
inherently designed to delimit or counterbalance each other in the development of
jurisprudence. Therefore, EU competition law may not be able to impugn the
Commission (Costen-Grundig) established the principle that “[t]he analysis under
EU competition law is not influenced by [the relative strength of intellectual
property rights] or by whether the relevant subject-matter is worthy of
protection.”645 In Consten-Grundig, the ECJ distinguished the grant of intellectual
property rights at the national level, which is not challenged under EU law, from
the exercise of these rights.646 Accordingly, as the law stands, the antitrust analysis
under Articles 101 and 102 of the TFEU is conducted on the assumption that the
intellectual property rights at issue are valid and infringed.647 Thus, patents are
deemed valid until proven otherwise. Lundbeck further confirms this principle by
stating that the existence of a patent does not mean that the generic manufacturer
(though having a firm intention and an inherent ability to enter the market and
demonstrating a readiness to challenge the validity of the patent) cannot be
characterized as a potential competitor.648 In the ECJ’s view, when the competition
authority assesses the intellectual property rights concerned for the purpose of
antitrust scrutiny, it must not conduct a review of the strength of the patent at issue
or of the probability of a dispute between the patent holder and generic

643. Colomo, supra note 420, at 596.
644. Id. at 599.
645. Id. (citing Joined Cases 56 & 58/64, Établissements Consten, S.A.R.L. v. Comm’n
(Costen-Grundig), 1966 E.C.R. 299; 345).
646. Id.; Consten-Grundig, 1966 E.C.R. at 345 (“[S]tating that the ‘Treaty shall in no way
prejudice the rules in Member States governing the system of property ownership.’ The
injunction . . . to refrain from using rights under national trade-mark law in order to set an
obstacle in the way of parallel imports does not affect the grant of those rights but only limits
their exercise to the extent necessary to give effect to the prohibition under Article 85 (1).”).
647. Colomo, supra note 420, at 599, 605.
citing Case C-307/18, Generics (UK) Ltd. v. Competition & Mkts. Auth., ECLI:EU:C:2020:52,
para. 46 (Jan. 30, 2020)).
manufacturers being brought to an end with a finding that that patent is valid and
has been infringed.649

Indeed, as the ECJ points out, the patent holder is legally free to conclude a
settlement agreement with an allegedly infringing party that does not exceed the
scope and duration of the remaining validity of that patent.650 Such agreement
represents the expression of the intellectual property rights of the patent holder.651
However, EU competition law may be able to regulate the way in which
intellectual property rights are exercised.652 The ECJ confirmed this by stating that
a “patent does not permit its holder to enter into contracts that are contrary to
Article 101 TFEU.”653 The ECJ held that the agreement between Lundbeck and
the generic manufacturers went beyond the specific subject matter of Lundbeck’s
intellectual property rights including “the right to oppose infringements, but not
the right to conclude agreements by which actual or potential competitors were
paid not to enter the market.”654 The ECJ found it unacceptable for the parties to
“attempt to mitigate the effects of legal rules which they consider excessively
unfavourable by entering into restrictive arrangements intended to offset those
disadvantages on the pretext that those rules have created an imbalance detrimental
to them.”655

U.S. antitrust jurisprudence sees a similar approach regarding the interaction
of patent law and antitrust law, specifically in the context of pay-for-delay
regulation. Any antitrust justifications based on patent law may not be acceptable
when they are to “reject the basic structure of the Court’s analysis.”656 The U.S.
Supreme Court in Actavis denied an assertion that the patent by itself affords
protection from antitrust scrutiny.657 The Court made it clear that its analysis is to

649. Id. para. 60 (citing Generics (UK), ECLI:EU:C:2020:52, para. 51).
650. Id. para. 124.
651. Id.
652. See Generics (UK), ECLI:EU:C:2020:52, para. 81.
653. Id. para. 97.
654. Case T-472/13, Lundbeck v. Comm’n, ECLI:EU:T:2016:449, para. 495 (Sept. 8,
2016).
655. Id. para. 387.
656. Edlin et al., supra note 134, at 19.
referred, simply to what the holder of a valid patent could do does not by itself answer the
antitrust question.”); id. at 149 (“Whether a particular restraint lies ‘beyond the limits of the
patent monopoly’ is a conclusion that flows from that analysis and not, as the Chief Justice
suggests, its starting point.” (emphasis in original)).
“accommodate patent and antitrust policies . . . .”\textsuperscript{658} The Court affirmed its approach of “seeking an accommodation ‘between the lawful restraint on trade of the patent monopoly and the illegal restraint prohibited broadly by the Sherman Act.’”\textsuperscript{659} Nevertheless, the Court did not open the way for patent policy-based defense.\textsuperscript{660} Even though the Court stated that it has answered antitrust questions, such as “whether ‘the patent statute specifically gives a right’ to restrain competition in the manner challenged,”\textsuperscript{661} contextualizing this statement from a holistic perspective signals that the Court was skeptical about concluding that patent law trumps antitrust law and is empowered to restrict competition.\textsuperscript{662} As the Court explained, the patent-related policy is “eliminating unwarranted patent grants so the public will not ‘continually be required to pay tribute to would-be monopolists without need or justification.’”\textsuperscript{663}

F. Admissibility of the Patent Strength Defense

\textit{Actavis} is in close line with \textit{Lundbeck} in that both take an adverse position to the admissibility of defense based on the strength of the patent, as is the case with the patent policy.\textsuperscript{664} The ECJ, in \textit{Lundbeck}, noted that the existence of a patent cannot be regarded as an insurmountable barrier, regardless of whether the patent is presumed to be valid.\textsuperscript{665} The court made clear that the competition authority need not review the patent strength or the probability that the patent will be found to be valid or infringed.\textsuperscript{666} The \textit{Actavis} Court stated that previous cases have analyzed the strength of patent to “demonstrate what would have happened to competition

\begin{itemize}
  \item \textsuperscript{658} \textit{Id.} at 137 (finding it “incongruous to determine antitrust legality by measuring the settlement’s anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well.”); \textit{id.} (“considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents.”); \textit{id.} at 151 (“seek[ing] to accommodate patent and antitrust policies, finding challenged terms and conditions unlawful unless patent law policy offsets the antitrust law policy strongly favoring competition.”).
  \item \textsuperscript{659} \textit{Id.} (quoting United States v. Line Materials Co., 333 U.S. 287, 310 (1948)).
  \item \textsuperscript{660} Edlin et al., \textit{supra} note 134, at 19.
  \item \textsuperscript{661} \textit{Actavis}, 570 U.S. at 147 (quoting \textit{Line Materials}, 333 U.S. at 311).
  \item \textsuperscript{662} Edlin et al., \textit{supra} note 134, at 19.
  \item \textsuperscript{663} \textit{Actavis}, 570 U.S. at 151 (quoting Lear Inc. v. Adkins, 395 U.S. 653, 670 (1969)).
  \item \textsuperscript{664} See \textit{id.} at 153; Case C-591/16, Lundbeck v. Comm’n, ECLI:EU:C:2020:428, para. 58 (June 4, 2020).
  \item \textsuperscript{665} Case C-591/16, Lundbeck v. Comm’n, ECLI:EU:C:2021:243, para. 58 (Mar. 25, 2021).
  \item \textsuperscript{666} \textit{id.} para. 60.
\end{itemize}
in the absence of the settlement." But the Court rejected the patent-strength approach. For example, defendants might not be permitted to argue that a settlement with a particular entry date creates as much competition as would be expected from litigation in cases where the patentee is likely to prevail in patent litigation. The Court stressed that litigating patent validity is normally not necessary to answer the antitrust question unless the litigation is a sham and the merit of the patent needs to be evaluated. As such, the patent-strength based defense is not admissible in the current antitrust jurisprudence and otherwise, “such a defense would defeat the Court’s stated purpose of cutting to the chase in these cases.”

G. Admissibility of the Risk Aversion Defense

Both Actavis and Lundbeck explicitly reject the risk-aversion defense. Defendants might argue that the patentee was highly risk-averse and therefore settled by paying more than avoided litigation expense in return for relatively early entry, which allowed consumers to enjoy more competition than would be anticipated from litigation. The patentee would rely on this argument “to avoid the risk of facing even more competition” if the patent was more than 50 percent expected to be held invalid. The settlement reduces competition because the agreed period of competition is smaller than what could be anticipated from the probability of the patentee losing the patent litigation. “[W]hat can be inferred is not that the patent is weak in any absolute sense, but rather that it is sufficiently weak that the settlement reduces competition in expectation, thereby depriving consumers of some of the benefits from competition.” Accordingly, the Actavis Court held that “even a small risk of invalidity” could not warrant such an unexplained, large payment because it purported to eliminate “the risk of

668. Id.
669. Edlin et al., supra note 134, at 19.
671. Edlin et al., supra note 134, at 19.
673. Edlin et al., supra note 134, at 20 (“[R]isk aversion could disturb the inference from the large settlement payment that the settlement entails less competition than litigation, because sufficient risk aversion can justify large payments to avoid small risks.”).
674. Id.
675. Id. at 17.
676. Id. (emphasis in original).
competition.”677 Thus, a reverse payment—in excess of avoided litigation costs to prevent even a small risk of competition—“constitutes the relevant anticompetitive harm.”678 The parties might have still settled the patent disputelawfully without the reverse payment. For instance, the parties might agree that the generic will delay market entry for an agreed period of time, but enter prior to the patent expiration without paying a royalty.679 The agreement to delay entry for less than the patent term is more likely to adequately reflect “the uncertain outcomes of patent litigation.”680 The parties can effectively divide up “the uncertainty costs of the litigation” based on the reasonable and realistic assessment of the likely outcome of the litigation.681 Consequently, the agreement without the exclusion payment, if reached, can lawfully make both parties better off without constituting antitrust violation.

In close parallel with Actavis, Lundbeck denies any risk-aversion defense. In Lundbeck’s argument, the agreements at issue legitimately purported to protect patents, though secondary not primary, by recourse to a “legitimate and commonplace means of dispute resolution” and the agreements were responding to an asymmetry of risks between the parties, which left the patentee in a position where it could not obtain full compensation for the loss caused by unlawful entry by the generics.682 Therefore, Lundbeck contended that the asymmetry of risks “justifie[d] settlements even where the patents concerned are objectively strong and infringed.”683 The argument that the agreements pursued legitimate objectives did not make the case viable. The acknowledged perception of the patent to be strong, questions the legitimacy of objectives. The patentee, sure of prevailing in patent litigation, would not pay potential competitors an amount more than reasonably anticipated litigation costs. As the ECJ explains, justifying the excessively large reverse payment requires additional explanation other than the

678. Id. Edlin et al., supra note 134, at 17; id. at 20 (“[R]isk aversion could disturb the inference from the large settlement payment that the settlement entails less competition than litigation, because sufficient risk aversion can justify large payments to avoid small risks.”).
679. See Actavis, 136 U.S. at 158; Hovenkamp et al., supra note 42, at 1762.
680. Hovenkamp et al., supra note 42, at 1762.
681. Id.
682. Case C-591/16, Lundbeck v. Comm’n, ECLI:EU:C:2021:243, paras. 104, 124 (Mar. 25, 2021). For general description of the settlement, see Colomo, supra note 420, at 601 (“A settlement is a contractual device that provides a title holder and an alleged infringer with an alternative way to address uncertainty. In accordance with an agreement of this kind, the alleged infringer may agree to leave the market or may delay market entry. In addition, there may be a value transfer. For instance, the alleged infringer may agree to compensate the title holder for any potential losses during the time its products were on the market.”).
joint commercial interest of the patentee and the generics not to engage in competition on the merits.684 Therefore, the alleged objectives do not vindicate the exclusion payment nor does the asymmetry of risks. The ECJ found the agreements at issue restrict competition, since by virtue of facilitating unexplained transfers of value; the agreements enabled competitors to “deliberately substitute practical cooperation between [the parties] for the risks of competition.”685 What makes these agreements more anticompetitive is that uninterrupted generic entry might have occurred despite the existence of a valid patent, as could be inferred from the ECJ’s finding. As noted above, the ECJ held that the mere existence of even a valid patent does not constitute an insurmountable barrier to entry that hinders the establishment of potential competition.686 The existence of potential competition postulates that the generics have “taken sufficient preparatory steps to enable [them] to enter the market” and to “impose competitive pressure” on the patentee.687 The probability of lawful generic entry, even prior to the expiration of the patent concerned, effectively refutes Lundbeck’s argument invoking anticipated loss of profits resulted from the generic’s infringement of a patent alleged to be strong enough to be ex ante held valid in litigation.

As such, one of the key inferences from Lundbeck, Paroxetine, as well as Actavis, is that the risk of competition based on the anticipated strength of a patent does not legitimately explain a large exclusion payment.688 The risk of competition by nature includes the probability generics can enter. The courts appear to share a common counterintuitive view that a pay-for-delay settlement may amount to a violation of antitrust law, irrespective of whether the patent is strong or weak, given that generic entry at risk may be considered lawful so long as there has not been a final ruling declaring that market entry would amount to a patent infringement. The EC notably takes the view that entry at risk is a valid expression of lawful competition on the merits.689 A reverse payment would frustrate generic entry at risk. One plausible criticism is that this view might expand the scope of prohibited practices falling within antitrust violations and create false positives.690 Indeed, potential competition would be deemed to exist in nearly every case, just

684. Id. para. 114.
685. Id. paras. 114, 134, 135, 167.
686. Id. para. 58.
687. Id. paras. 57, 84.
689. Colomo, supra note 420, at 607.
690. Id.
as generic entry at risk would be presumptively lawful. An inevitable consequence would be that a pay-for-delay settlement would amount to a violation of antitrust law, regardless of whether the patent dispute concerned is genuine or not. The Commission in *Lundbeck* and the CMA in *Paroxetine* argued that “potential competition can be shown to exist even when, as a matter of fact, entry involves the use of a patented process.” This expansive interpretation of the notion of competition as advanced by both the Commission and CMA “appears to equate an uncertain probability of market entry with likely entry.” This interpretation would create controversy by eliminating (or at least blurring) the line between genuine and non-genuine settlements.

However, both *Lundbeck* and *Paroxetine* state it is not necessary to demonstrate with certainty that competitors would have entered the market and entry would inevitably have been successful, but only that competitors had real and concrete possibility. In other words, what needs to be proved is whether competitors have a firm intention and an inherent ability to enter the market and do not meet barriers to entry that are insurmountable. In this sense, whether the patent dispute is genuine concerns that no other alternatives, for instance, non-patented processes to manufacture generic drugs, are available as that would matter in assessing potential competition. EU competition law requires separate intensive inquiry into potential competition on the merits. By contrast, whether potential competition exists is not a separate question the competition authority or the court asks when conducting analysis under U.S. antitrust law. This issue is rather treated as an integral part of the broader issues: the assessment of power and competitive effect. In other words, whether the parties are potential competitors is determined as an inherent issue in the context of the assessment of competitive effect and market power. Furthermore, *Actavis*’ inference clearly establishes the notion that the risk of invalidity incentivizes the branded to settle a patent dispute with the generic by means of a large payment, which acted as a limitation on the

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691. *Id.* at 606.
692. *Id.* at 608.
693. *Id.* at 606, 608.
694. *Id.* at 608.
generics’ ability to compete. Therefore, the risk of competition is of fundamental significance in establishing the legality of patent dispute settlement from an antitrust perspective. Entry at risk prior to the patent expiration would further the level of competition, but it would leave no antitrust concern if even the generic chose not to enter at risk on the basis of its own undisturbed assessment of the likely outcome of the litigation. Antitrust law, by contrast, intervenes where entry at risk is frustrated by the branded devising an inducement to limit the generic’s commercial autonomy. In this respect, Actavis theoretically leaves no room for any possibility of false positives at least in terms of the risk of competition.

V. CONCLUSION: PIONEERING A NEW PATH TO RULE ELABORATION AND CLARIFICATION

Revamping and redesigning current antitrust rules to form a more sustainable and well-functioning legal framework is matter of how to do what. That said, to put it bluntly, it is a matter more of how and less of what. This is because an answer to “what to do” was already given at presence. Actavis and Lundbeck represent the prevailing rule of the highest authority on either side of the Atlantic; therefore, they are the rules to start with. By contrast, “how to” seems to be not an easy question to answer. A close look at both Actavis and Lundbeck through a critical lens clearly shows a silver lining for the breakthrough. Contrary to the up-to-date general notion that both decisions stand out in high integrity as the dominant rule on the soil of their respective jurisdictions, they leave prominently critical loopholes, whether or not identical to each other, that can be best filled by having both sides learn from each other. The rule complementarity inevitably requires rule comparison and integration. In other words, the initiative to recalibrate the legitimacy and validity of current antitrust rules for patent dispute settlement regulation calls for an answer to the inevitable question as to how to compare and integrate Actavis and Lundbeck.

With this recognition, this Article thoroughly investigated antitrust law and policy in the United States and European Union and strived to identify where they converged and diverged and how they informed each other to form a harmonious, sustainable, and well-structured legal framework. This Article revealed that the critical examination of convergence and divergence that led to the transatlantic

699. Edlin et al., supra note 224, at 1.
700. Id. at 4.
development of jurisprudence as opposed to intensifying further complexity that might have occurred if the law and policy across the Atlantic Ocean had failed to share the common essence in carving out the effective rules due to the want of reciprocal and complementary approaches. This Article proved the validity and feasibility of rule synthesis by showing that both the U.S. and EU laws were looking ahead toward the same path to rule clarification and elaboration. More specifically, reading *Actavis*, *Lundbeck*, and further *Servier*, jointly from a complementary perspective, offers important inferences contributing to the establishment of the integrative overarching framework and effectively advancing the consistent and coherent development of antitrust jurisprudence.703 How reverse payment antitrust rules can best benefit from the transatlantic integrated approach is cogently and coherently explained with legal implications as set forth in seven key aspects.704 The size of reverse payment, among other things, merits special salience and additional attention.705 The size of the unexplained reverse payment provides “a workable surrogate” for the weakness of the patent and lost competition; the size of the payment is likewise a proxy for market power.706 Both *Actavis* and *Lundbeck* take the payment approach as opposed to the patent-strength approach.707 The payment approach is implemented against the litigation cost benchmark.708 The *Actavis* inference sets out the general principle that reverse payments to avoid even a small risk of competition are anticompetitive insofar that the amount of payment exceeds anticipated litigation expense.709 However, *Lundbeck* expands this principle to accommodate a reasonable magnitude of flexibility in defining the size of the reverse payment.710 Thus, it is noted that even the payment of an amount less than the expected profits is still subject to antitrust condemnation.711 The size of exclusion payment need not necessarily be greater under the settlement than the damages that could have been paid if it had successfully prevailed in patent litigation.712 Likewise, the exclusion payment does not have to amount to the profits that the generic would have made if it had entered

711. *Id.*
712. *Id.* para. 115.
the market. *Lundbeck*’s supplement to *Actavis* principles holds that such payments of an amount less than the expected profits or damages still constitute a certain and immediate profit by effectively preventing the generics from entering the market at risk.\(^{713}\) This represents one of the legal loopholes that remain wide in either side’s jurisprudence that may unnecessarily result in arbitrary interpretation or rule manipulation and consequently disrupt coherent and consistent antitrust enforcement.

In light of the robust interaction between competition law and IP law, the case law established through *Actavis*, *Lundbeck*, and *Servier* affords joint and complementary insights into the appropriate framework for antitrust analysis of reverse payment settlements. The accumulation of jurisprudence reveals the complex dynamics of the settlements mainly due to their particular nature arising from such antitrust-IP interplay and vindicates the consideration of a flexible approach on a case-by-case basis. The reverse payment antitrust scrutiny calls for the multifaceted evaluation of the settlement at issue with an array of variables mobilized and assessed. Such factors may include, *inter alia*, whether the patent at issue is primary or secondary, whether it has expired or is valid, whether the patent dispute is genuine or not, and whether the reverse payment is linked to a genuine patent settlement or non-genuine one. There is no simple answer or test for those questions. As *Actavis* points out with prudence, how the analytical method is designed, formulated, and implemented would depend completely upon a case-by-case evaluation.\(^{714}\) Close attention is needed to ensure that the following evaluation is neither too equivocal nor too simplistic but be comprehensive and flexible enough to embrace the consideration of relevant factors from multifarious aspects.\(^{715}\)

In sum, shared antitrust rules between the United States and European Union confirm that reverse payment settlements generally fall within the scope of anticompetitive patent practice with exceptions for the marginal cases. The key rationale behind antitrust regulation of reverse payment settlements is that they substantially harm market competition and consumer welfare.\(^{716}\) Thus, reverse payment settlements with an anticompetitive potential fall afoul of the competition

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713. *Id.* para. 135.


715. *Id.* at 159–60 (suggesting the flexible antitrust analysis “to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences.”).

716. *Id.* at 157.
policy of those countries whose cardinal objective is to enhance economic efficiency and consumer welfare by promoting competition in the market and eliminating certain behaviors that hinder competition in the market. Antitrust concerns over reverse payment settlements in the United States were, more vigorously than before, addressed under the drug approval-patent linkage scheme introduced with the enactment of the Hatch-Waxman Act in 1984.\textsuperscript{717} Notably, the anticompetitive dynamics of reverse payment settlements problematically manipulate the drug approval-patent linkage scheme by allowing the unique generic exclusivity mechanism to function contrary to the intended purpose as an institutional barrier to the promotion of robust market competition and further the innovation of pharmaceutical technology by blocking subsequent market entry of other generics. Generic exclusivity was originally introduced to ensure the first generic entrant temporary limited protection from wide-open potential competition during the 180-day period. However, a for-supra-profit-sharing consensus between the branded and generic firms has since induced heavy reliance upon a myriad of reverse payment settlements, which are facilitated by the misuse of the generic exclusivity mechanism. This perverse incentive has manipulated and undermined the approval-patent linkage scheme and consequently thwarted pharmaceutical competition to the detriment of non-settling firms and consumers. Since the enactment of the Hatch-Waxman Act, the FTC’s effort for antitrust enforcement has materialized in a wide array of investigations concerning reverse payment settlements. A significant number of decisions the FTC adopted following investigations were appealed to the courts, which eventually led to the robust accumulation of case law. In particular, the U.S. Supreme Court’s epoch-making decision in \textit{Actavis} set a precedent for establishing antitrust rules to regulate reverse payment settlements. Akin to the U.S. regulatory landscape, the EU antitrust jurisprudence has captured robust regulatory dynamics of reverse payment settlements, but they have played out without contextual relevance to the approval-patent linkage equivalent. The discrepancy in regulatory mechanism notwithstanding, how the EU law and policy frame antitrust concerns over reverse payment settlements shows no deviation from the U.S. counterpart.

Regulatory efforts to combat anticompetitive patent practice have driven steadfast antitrust enforcement in the United States and European Union and led to the development of jurisprudence within and across jurisdictions. Joint interpretation of \textit{Actavis} and \textit{Lundbeck} substantiates that the transatlantic interaction of antitrust law has been advanced through mutual recognition and accommodation. Both decisions share common inferences and perspectives as opposed to drawing parallel lines. The new paradigm to approach reverse payment issues calls for progressive antitrust that favors coexistence and harmony rather

\textsuperscript{717} See \textit{supra} Part II.
than disaccord and confrontation. Thus, antitrust rules having coterminous boundaries are preferably subject to critical evaluation to determine whether they collide or complement. In other words, progressive antitrust looks to a new path toward jurisprudential convergence. Expanding the horizon beyond jurisdictional bounds is inevitable to achieve rule clarity and integrity, which collectively leads to the rule’s stability. This is even more so given the reality that emerging business tactics tend to be more internationalized. A firm facing legal or regulatory intervention in their country can move readily to establish a joint venture in partnership with a foreign-based firm or relocate the principal place of business to a foreign country. Building an integrative legal framework by facilitating feedback exchange between established rules can be an effective solution to forum shopping based on anticompetitive or unfair purposes although it may not be a panacea in every circumstance.

Structural rigidness and doctrinal exclusivity destabilize and challenge the law by creating legal vulnerability to external variables. It follows that the law is likely to isolate itself from further development. Paradoxically, this internal imperfection can be counterbalanced only by legal flexibility stemming from the accommodation of external complementary rules. It is noteworthy that old wisdom says standing pools gather filth. Lundbeck manifestly built its analysis partially on the Actavis inference, and this transatlantic judicial deference indicated the potential for further vigorous interaction across the Atlantic to bridge the rule gap and rejuvenate the body of antitrust law. Ensuring flexibility in rule development under the complementary and reciprocal approach can best shed light on the significance of milestones Actavis and Lundbeck represented on the continuing initiative to achieve legal and regulatory unity for cross-border antitrust enforcement against reverse payment settlements.