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I. INTRODUCTION

After more than a decade of debate and complex litigation on "reverse payment" settlements, the Supreme Court ruled on the issue in *Federal Trade Commission v. Actavis, Inc.*[2] The pharmaceutical industry now asks: So, are those settlements lawful? The *Actavis* Court's answer: "Depending on the circumstances, a reverse payment settlement can be lawful . . . or unlawful."

The lower courts are now commissioned to apply the decades-old rule of reason to reverse payment settlements and, in the process, to advance important antitrust and intellectual property interests.

At almost the same time that the Supreme Court issued the *Actavis* decision, the European Commission announced its *Lundbeck* decision that found a collection of reverse payment settlements unlawful.[3] Vice President Almunia lauded a convergence of the U.S. and European approaches to the arrangements: case-by-case and factually intensive.

This article reviews *Actavis* and the European announcement on the *Lundbeck* decision. It then discusses the case-by-case approach that lower courts in the United States and future Commission decisions might employ in evaluating reverse payment settlements and advancing antitrust and patent policy objectives.

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[2] *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

[3] Case COMP/ AT. 39226 – *Lundbeck*, European Commission Decision of 19 June 2013. No public version available.

II. THE SUPREME COURT'S RULING IN ACTAVIS

A. Background: The Eleventh Circuit's "Scope-of-the-Patent" Test

In *Federal Trade Commission v. Watson Pharmaceuticals, Inc.*[4] (the "AndroGel" decision), the Eleventh Circuit dismissed the FTC complaint that the settlement agreement between Solvay Pharmaceuticals, the patent holder for a brand-name drug called AndroGel, and generic firms, Actavis (also known as Watson Pharmaceuticals) and Paddock Laboratories, violated the antitrust laws.

Under the terms of the agreement, the generic firms agreed not to sell generic Androgel until five years before Solvay's patent expired.[5] According to the FTC, Solvay agreed to pay "millions of dollars" to each generic, which constituted the so-called reverse payments that were designed to compensate the generic firms for staying out of the market.[6]

In accordance with the Eleventh Circuit's prior decisions on the subject and the decisions of the Second and Federal Circuits, the Eleventh Circuit dismissed the FTC's complaint as legally deficient for having failed to state a valid antitrust claim. The main flaw, according to the Eleventh Circuit: The FTC did not allege that the settlement agreement between Solvay and the generic companies included a restriction on the commercial conduct of the generic companies that exceeded the claim in the patent at issue in the litigation.[7]

The Eleventh Circuit thus stated unambiguously: "[A]bsent 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."[8]

B. The Supreme Court Rejected the "Scope-of-the-Patent" Test

The Court started its analysis by rejecting the "scope-of-the-patent" test: Agreements are not immune from antitrust attack simply because their "anticompetitive effects fall within the scope of the exclusionary potential of the patent."[9] In its place, the Supreme Court announced a new assessment: "In our view, . . . reverse payment settlements such as the agreement alleged in the complaint before us can *sometimes* violate the antitrust laws."[10] As a result, reverse payment settlements are to be evaluated under the rule of reason.

The Court addressed the legal issue with a view of accommodating both antitrust and patent policies, not only the patent policies that the Court found to underlie the Eleventh Circuit's antitrust-immunity rule. Antitrust law favors competition and low prices. Patent law

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[4] 677 F.3d 1298 (11th Cir. 2012).

[5] *Actavis,* 133 S. Ct. at 2229.

[6] *Id.*

[7] *AndroGel,* 677 F.3d at 1312 ("The FTC argues that its 'not likely to prevail' allegation sufficiently states an antitrust claim because a patent has *no* exclusionary potential if its holder was not likely to win the underlying infringement suit. . . . We decline the FTC's invitation and reject its argument."); *see also id.* at 1310 ("The essence of [this Court's] analysis is an evaluation of whether the settlement agreements contain provisions that restrict competition beyond the scope of the exclusionary potential of the patent.").

[8] *Id.* at 1312.

[9] *Actavis,* 133 S. Ct. at 2230 (quoting *AndroGel*, 677 F.3d at 1312).

[10] *Id.* at 2227 (emphasis added).

favors innovation and invention. Lower courts are to apply the rule of reason in a manner that accommodates and promotes both competition and innovation.

At the core of the Supreme Court's rejection of the antitrust-immunity rule were five "considerations" regarding reverse payment settlements:

- First, reverse payment settlements have the potential for "genuine adverse effects on competition," thereby fundamentally rendering the antitrust-immunity rule inappropriate. The Court credited the FTC's allegations: "[S]ettlement on the terms said by the FTC to be at issue here—payment in return for staying out of the market—simply keeps prices at patentee-set levels, potentially producing the full patent-related . . . monopoly return while dividing that return between the challenged patentee and the patent challenger."[11]

  In discussing the first consideration, the Court stated that two "special features" of the Hatch-Waxman Act may impede other challengers from demanding their own reverse payments from the brand company.[12] The Court concluded that "Hatch-Waxman's unique regulatory framework" may do "much to explain why . . . the patentee's ordinary incentives to resist paying off challengers . . . appear to be more frequently overcome."[13]

- Second, the Court stated that "the anticompetitive consequences will at least sometimes prove unjustified," though it also acknowledged that "offsetting or redeeming virtues are sometimes present."[14] Those virtues could include, but are not limited to, compensation for the litigation costs saved through the settlement or "fair value for services" performed by the generic challenger in the context of the settlement. The Court concluded its second consideration by expressly acknowledging that a reverse payment in a settlement agreement can be shown to be lawful under the rule of reason.[15]

- Third, the Court addressed market power—the power to charge prices that are higher than competitive levels—and thereby highlighted the importance of such power in harming competition. In that regard, the Court observed that such market power may be indicated by a willingness by the brand company to pay "large sums" to "induce others to stay out of its market."[16]

- Fourth, the Court stated that "normally" "patent validity" need not be litigated "to answer the antitrust question. . . . An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be

[11] *Id.* at 2234-35.

[12] *Id.* at 2235.

[13] *Id.*

[14] *Id.* at 2235-36.

[15] *Id.* at 2236 ("An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.").

[16] *Id.*

shared among the patentee and the challenger rather than face what might have been a competitive market . . . ."[17]

- Fifth, the Court observed that parties can "settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point."[18]

C. The Supreme Court Charted a Middle Course, Rejecting the FTC's Proposed Presumption of Illegality and Adopting a Full Rule-of-Reason Framework

After rejecting the Eleventh Circuit's antitrust-immunity rule, the Court also rejected the FTC's suggestion that reverse payment settlements are presumptively unlawful. Instead, the Court held that "the FTC must prove its case as in other rule-of-reason cases."[19]

In conducting such an analysis, the Court expressed particular interest in "the likelihood of a reverse payment bringing about anticompetitive effects."[20] The Court continued that such effects "depend[] upon [the] size [of the payment], 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."[21]

Aside from that general guidance, however, the Court delegated to the lower courts the responsibility of "structuring" the application of the rule of reason to reverse payment settlements, noting that the rule of reason can be tailored to meet the needs of each case.[22]

III. STRUCTURING A RULE-OF-REASON TEST

The rule of reason has formed the core of antitrust analysis for almost a century. That analysis has evolved over the years, but, for the last forty years, the rule of reason has increasingly focused on whether the restraint in question reduces "consumer welfare" within a properly defined relevant market. Consumer welfare is generally understood as the level of output (broadly viewed in terms of the quantity, quality, and prices of the goods or services in questions) within the relevant market.

Professor Alan Sykes, who recently served as a court-appointed expert in the payment-card litigation in the Eastern District of New York,[23] captured well, in his report to the court, the "question" properly posed by the rule of reason: "[T]he question is what *market equilibrium* would emerge if the alleged anticompetitive practices were eliminated, and how that equilibrium would compare from an economic standpoint to the *status quo* [where the restraint is present]."[24]

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[17] *Id.*
[18] *Id.* at 2237.
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.* at 2237-38.
[23] Order, In re Payment Card Interchange Fee & Merchant Discount Antitrust Litigation, No. 05-md-01720-JG-JO (E.D.N.Y. Apr. 8, 2013), ECF No. 2087.
[24] Memorandum to Hon. John Gleeson, In re Payment Card Interchange Fee & Merchant Discount Antitrust Litigation, No. 05-md-01720-JG-JO, at 22 (E.D.N.Y. Aug. 28, 2013), ECF No. 5965.

Indeed, that question has been central to the overall development of antitrust jurisprudence and informs such important doctrines as antitrust standing and injury (does the plaintiff's alleged harm arise from a market injury or is it only a personal injury to the plaintiff?).

Intent alone has never been sufficient to condemn a practice. Even with respect to attempted monopoly, the Court was unwilling to infer a dangerous probability of monopolization—the anticompetitive effect—from a *specific intent* to monopolize and required a separate showing of likely impact on competitive conditions.[25]

Almost 100 years ago, Justice Brandeis provided the paradigmatic description of the rule of reason, emphasizing the importance of the "conditions before and after the restraint was imposed" and that "intention" will not save or condemn a restraint but may be probative of its effects:

> The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; *its condition before and after the restraint was imposed*; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts. This is not because a good intention will save an otherwise objectionable regulation or the reverse; but because *knowledge of intent may help the court to interpret facts and to predict consequences*.[26]

The anticompetitive harm in a reverse payment settlement cannot be solely the elimination of the risk that a competitive market would result from the litigation, as the Court welcomed settlements without reverse payments.[27] All such settlements necessarily prevent the emergence of a competitive market before the agreed-upon entry date.

Rather, the Court referenced a fundamental question to be answered by the rule-of-reason assessment in its fifth consideration: Does the payment cause the challenger to stay out of the market for longer than it likely would have stayed out of the market in the absence of the payment?[28] The Court rejected all presumptions in answering that question. Instead, the answer must be proved by the plaintiff with competent, non-speculative evidence.

Lower courts will determine what evidence they will admit and consider to demonstrate "what *market equilibrium* would [have] emerge[d] if the [reverse payment had been] eliminated, and how that equilibrium would compare from an economic standpoint to the *status quo* [where the reverse payment is present]."[29]

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[25] *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 457-58 (1993) (holding that a dangerous proof of monopolization requires proof of more than specific intent).

[26] *Bd. of Trade of Chi. v. United States*, 246 U.S. 231, 238 (1918) (emphasis added).

[27] *Actavis,* 133 S. Ct. at 2237 (Litigating parties "may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point.").

[28] *Id.*

[29] Memorandum to Hon. John Gleeson at 22.

IV. THE EUROPEAN APPROACH

The European Commission has gone farther than the Supreme Court. It has found that a collection of reverse payment settlements in fact violated Article 101 of the TFEU, not just that such agreements *can violate* Article 101. The recently announced case involved the blockbuster antidepressant, citalopram, and settlement agreements between Lundbeck and several generic firms; the European Commission imposed fines totaling close to U.S.$200 million.

The European Commission, however, does not have the last word, and Lundbeck and the generic firms have filed an appeal that will be reviewed by the European General Court. No doubt, the correct legal analysis of such settlements will be central to that appeal.

Other European investigations of patent settlement agreements are pending. Guidance as to the European Commission's mode of analysis might be found in commentary offered by Vice-President Joaquin Almunia upon the announcement of the *Lundbeck* decision. He explained that the Commission established a *per se* prohibition for "out-of-scope" agreements—those with restrictions that exceed the claims in the patent—but a case-by-case analysis was appropriate for other settlement agreements.[30]

Vice-President Almunia also suggested that the European Commission's approach was consistent with the U.S. *Actavis* decision and that the Commission hoped that the *Actavis* decision reflected "the line that in the future the European Court of Justice will decide."[31]

The declarations of the European Commission thus seem to suggest that European competition authorities will follow an analysis tailored to the specific facts, and likely effects, of each settlement agreement. That analysis should pivot upon the answer to the question of what effects would likely have ensued in the absence of the reverse payment in a manner that is similar to the operation of the rule of reason in the United States. That question can be properly assessed only in light of the factual, legal, and economic background in which the settlement was reached.[32]

V. CONCLUSION: ANTITRUST AND PATENT POLICY CONSIDERATIONS SHOULD BE ADVANCED THROUGH AN EFFECTS-BASED, RULE-OF-REASON ASSESSMENT

By answering the question of how competition likely would have ensued in the absence of the reverse payments, courts would accommodate the apparently conflicting policy concerns of intensive price competition and innovation. Investment in product development and entry should not be deterred, and on-market competition should be promoted, if settlements are

[30] Mlex - June 19, 2013 ("In this particular case, the patent … had expired when Lundbeck had paid the generic competitors to get non-entry into the market … [In] some other cases, you can have some payments that can be also anticompetitive, but this requires a case-by-case approach.").

[31] Mlex - June 19, 2013.

[32] The question of competitive harm may also be affected in Europe by the absence of statutory exclusivity to the first generic manufacturer to file for or obtain regulatory approval. In *Actavis* the Court noted the relevance of the Hatch Waxman Act to its analysis of possible anticompetitive effects. *Actavis,* 133 S. Ct. at 2235. The European Commission likewise should recognize the relevance of the absence of a similar regime in Europe, which reduces the likelihood that a particular settlement can delay entry. Given that the likelihood of anticompetitive effects resulting from the restriction is central to its assessment under European competition law, a particularly careful analysis of the factual, legal, and economic circumstances surrounding each settlement should be conducted in each instance.

prohibited only where the plaintiff proves with competent, non-speculative evidence that lawful entry would have occurred earlier in the absence of the payment.