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I. INTRODUCTION

In June, the Supreme Court ruled 5-3 in favor of the Federal Trade Commission in *FTC v. Actavis, Inc.* Writing for the majority (that included Justices Kennedy, Ginsburg, Sotomayor, and Kagan), Justice Breyer's opinion reversed the decision of the Eleventh Circuit Court of Appeals dismissing the FTC's complaint that a "reverse payment" settlement agreement between an innovator drug maker and generic challengers in ANDA litigation was anticompetitive and violated the antitrust laws.

The decision was not a decisive victory for the Commission, however: The Court refused to accept the FTC's position that such agreements are presumptively unlawful, holding that lower courts should apply an antitrust "rule of reason" analysis when evaluating such agreements.

II. RECAP: LITIGATION IN THE DISTRICT COURT FOR THE NORTHERN DISTRICT OF GEORGIA

The underlying litigation involved a reverse payment settlement between NDA holder Solvay Pharmaceuticals and ANDA filers Watson Pharmaceuticals and Paddock Pharmaceuticals. Watson and Paddock filed separate ANDAs having Paragraph IV certifications that U.S. Patent No. 6,503,894 was invalid or unenforceable, and the patent holder timely filed suit pursuant to 35 U.S.C. § 271(e)(2) in the U.S. District Court for the Northern District of Georgia. However, the parties settled before the Court could rule on defendants' summary judgment motions.

The agreement specified that defendant generic drug companies would "respect" the '894 patent, and that both were entitled to launch in August 2015, five years before the '894 patent was scheduled to expire. In addition, Watson and Paddock agreed that their sales forces would promote Solvay's product until the agreed time for their own product launch, and that Solvay would make annual payments to each generic company (~$20-30 million to Watson, ~$10 million to Par/Paddock), and that Par/Paddock would supply the drug to Solvay in a "backup capacity" for an additional $2 million annually.

The FTC alleged violations of Section 5a of the Federal Trade Commission Act under 15 U.S.C. § 45(a)(1) and brought suit. The District Court granted defendants' motion to dismiss for failure to state a claim, consistent with the 11th Circuit's precedent in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*,[2] and *Schering-Plough Corp. v. Federal Trade Commission*,[3] that these agreements are lawful "so long as the terms of the settlement remain within the scope of the

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[2] *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003)

[3] *Schering-Plough Corp. v. Federal Trade Commission*, 402 F.3d 1056 (11th Cir. 2005)

exclusionary potential of the patent, *i.e.*, do not provide for exclusion going beyond the patent's term or operate to exclude clearly noninfringing products, regardless of whether consideration flowed to the alleged infringer."

In doing so, the District Court rejected the FTC's contentions in its complaint "(1) that the settlement agreement between Solvay and Watson is an unfair method of competition; (2) that the settlement agreement among Solvay, Paddock, and Par is an unfair method of competition; and (3) that Solvay engaged in unfair methods of competition by eliminating the threat of generic competition and thereby monopolizing the market."

III. COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

The 11th Circuit affirmed, holding 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." The Court assessed (and rejected) the FTC's allegations under this standard, noting those allegations to be: (1) that Solvay was "unlikely to prevail" in the underlying patent infringement litigation; (2) that accordingly the patent has "<u>no</u> exclusionary potential" (emphasis in original); and (3) if a patent has no exclusionary potential, the reverse payment arrangement "necessarily" exceeds its "potential exclusionary scope" and thus is tantamount to "'buying off' a serious threat to competition."

The FTC urged the Court, according to the opinion, "to adopt 'a rule that an exclusion payment is unlawful if, viewing the situation objectively as of the time of the settlement, it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date.'" The Eleventh Circuit found the Commission's allegations to be unfounded and affirmed the District Court's dismissal of the government's complaint.

IV. SUPREME COURT

The FTC petitioned for certiorari, the Question Presented being:

> Whether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud (as the court below held), or instead are presumptively anticompetitive and unlawful (as the Third Circuit has held).

A. The Majority Opinion

In the majority opinion, Justice Breyer wrote that reverse payment settlement agreements can "sometimes violate the antitrust laws," and thus that the District Court should not have dismissed the case brought by the FTC. The opinion focused on the risk to the consuming public posed by such settlements in cases where the patent is invalid or not infringed. According to the majority, although they were willing to accept that the agreement's "anticompetitive effects fall within the scope of the exclusionary potential of the patent," this fact is not sufficient to "immunize the agreement from antitrust scrutiny."

The majority's concern was that while the holder of a *valid* patent may be exempt from antitrust liability when enforcing the exclusionary right, ANDA litigation involves an allegation that either the patent is invalid (in which case the immunization is lost) or the generic product does not infringe (in which case the patent cannot be enforced against the non-infringing generic drug). Accordingly, such agreements "tend to have significant adverse effects on competition." For these reasons, the majority believes that "it would be 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."

In Justice Breyer's opinion, support for this proposition (vigorously disputed by the dissenting Justices; *see below*) is found in several of the Court's earlier cases, *including United States v. Line Material Co.*,[4] (retail price-setting between patentees); *United States v. United States Gypsum Co.*,[5] and *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*[6] (a case that established one of the grounds for finding reverse payment settlement agreements unlawful, *i.e.*, asserting a patent obtained by "fraud on the Patent Office").

The opinion also cited several earlier cases where settlement agreements (not in the Hatch-Waxman context) were held to violate the antitrust laws. In addition to this precedent, which the majority used to support the proposition that settlement "agreements are not outside the scope of antitrust scrutiny" the Court found that the "procompetitive" purposes of the Hatch-Waxman Act are consistent with having courts apply antitrust principles to reverse payment settlement agreements in ANDA litigation.

Turning to the "general legal policy favoring the settlement of disputes," Justice Breyer's opinion does not find sufficient force in this policy to override the majority's concerns regarding anticompetitive effects of reverse payment settlement agreements, even though the majority recognizes the Eleventh Circuit's concern that "antitrust scrutiny of a reverse payment agreement would require the parties to litigate the validity of the patent in order to demonstrate what would have happened to competition in the absence of the settlement," an outcome that "will prove time consuming, complex, and expensive." In response to this concern, the majority offered five "considerations" as a basis for its holding that the FTC should be permitted to establish an antitrust violation under some circumstances:

1. "*First*, the specific restraint at issue has 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.

   The opinion also states this concern as "[t]he patentee and the challenger gain; the consumer loses," citing academic sources and *amicus* briefs for the proposition that "there are indications that patentees sometimes pay a generic challenger a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market." Under these circumstances, "a payment of this size [] 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." And the majority disparaged the idea that entering into such an agreement

[4] *United States v. Line Material Co*., 333 U. S. 287, 308 (1948).
[5] *United States v. United States Gypsum Co*., 333 U. S. 364, 390–391 (1948).
[6] *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp*., 382 U. S. 172, 174 (1965).

would merely entice other generic challengers to get in line to be bought off by the patentee, based on the loss of the 180-day exclusivity for later ANDA filers and the 30-month delay in FDA approval raised by ANDA litigation against such a subsequent filer.

These considerations convinced the majority that, rather than producing an untenable situation where the owner of a weak patent cannot possibly "buy [] off" all potential competitors, the Hatch-Waxman regime in fact produces a critical generic challenger, the first filer, who if successfully bought off by a reverse payment settlement agreement will effectively chill future challenges by other generic drug makers.

2. *"Second*, these anticompetitive consequences will at least sometimes prove unjustified." The majority's concern is that a court cannot tell without inquiry whether a particular reverse payment settlement agreement is or is not "justified" under antitrust principles. "Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement. In such cases, the parties may have provided for a reverse payment without having sought or brought about [] anticompetitive consequences."

   This uncertainty is the basis for the majority to conclude that the District Court erred in dismissing the FTC's complaint, because by doing so it denied the Commission the chance to establish whether or not there were such justifications for the agreement.

3. "*Third*, where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice." Once again the majority is concerned with the size of the payment, which a court can use to be "a strong indicator of [market] power."

4. "*Fourth*, an antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed." Here the majority finds the Eleventh Circuit "throws the baby out with the bathwater" by refusing to apply antitrust principles due to the difficulties of litigating patent infringement and validity. According to the majority, "it is normally not necessary to litigate patent validity to answer the antitrust question" (except for sham litigation), because "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival."

5. "*Fifth*, the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit."

   Here, the majority posits that the parties can settle an ANDA dispute in "other ways, [] 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." Once again the majority return to the existence of a payment, saying that "the basic antitrust question" comes down to the reasons for the payment (and, of course, a court's determination of whether those reasons are valid).

The majority summarizes these considerations as follows:

> In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be

> unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments. In our view, 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.

B. Rejecting the FTC's Presumptively Unlawful Request

The FTC did not entirely win the day with the majority, however, who rejected the Commission's suggestion that these agreements should be presumptively unlawful and that the rule of reason be applied using a "quick look" or other shortcut, which the majority noted was permissible only in instances 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," citing *California Dental Assn. v. FTC*[7].

This treatment is not justified for reverse payment settlement agreements according to the majority, because "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."

Instead, these Justices hold that the FTC must establish antitrust liability using a "rule of reason" analysis, and in doing so, district courts can structure the inquiry to avoid litigating patent validity, leaving it to these "lower" courts to determine exactly how that may be accomplished.

C. The Dissent

The Chief Justice wrote the dissent, joined by Justices Scalia and Thomas (Justice Alito recused himself from this case). Applying much of the same precedent, the dissent came to the opposite conclusion: the existence of a patent, properly cabined within its proper scope, should be enough to justify a reverse payment settlement of ANDA litigation. Instead of following "well-established" principles of patent law, the dissent asserted that the majority would "use antitrust law's amorphous rule of reason to inquire into the anticompetitive effects of such settlements."

Besides finding no support in the patent law or other statute, the dissent objected to the majority's ruling because it "will discourage the settlement of patent litigation." Patent law "provides an exception to antitrust law, and the scope of the patent—i.e., the rights conferred by the patent—forms the zone within which the patent holder may operate without facing antitrust liability. This should go without saying," according to the Chief, "in part because we've said it so many times," citing *Walker Process*, *Line Mineral*, *General Electric*, *Union Oil* and *Standard Oil*. The only times a settlement had been found to violate antitrust law in past Supreme Court precedent were when the settlement went beyond the boundaries of the patent grant say the dissenters, citing *Singer Mfg. Co.*, unless the patents were obtained by fraud (*Walker Process*) or the patentee engaged in sham litigation, *citing Professional Real Estate Investors, Inc. v. Columbia*

[7] *California Dental Assn. v. FTC*, 526 U. S. 756, 775 (1999)

Pictures Industries, Inc.[8] For the dissenting Justices, the history of the application of antitrust law in the patent context is telling:

> The majority is therefore right to suggest that these "precedents make clear that patent-related settlement agreements can *sometimes* violate the antitrust laws." Ante, at 10 (emphasis added). The key word is sometimes. And those some times are spelled out in our precedents. Those cases have made very clear that patent settlements—and for that matter, any agreements relating to patents—are subject to antitrust scrutiny if they confer benefits beyond the scope of the patent. This makes sense. A patent exempts its holder from the antitrust laws only insofar as the holder operates within the scope of the patent. When the holder steps outside the scope of the patent, he can no longer use the patent as his defense. The majority points to no case where a patent settlement was subject to antitrust scrutiny merely because the validity of the patent was uncertain. Not one. It is remarkable, and surely worth something, that in the 123 years since the Sherman Act was passed, we have never let antitrust law cross that Rubicon.

According to the Chief, "settling a patent claim *cannot possibly* impose unlawful anticompetitive harm if the patent holder is acting within the scope of a valid patent and therefore permitted to do precisely what the antitrust suit claims is unlawful" (*emphasis in opinion*).

And thus the dissenting Justices contend that the majority's fancy that the antitrust question can be answered without considering the validity of the patent is unrealistic, and "depriving [the patentee] of such a defense—if that's what the majority means to do—defeats the point of the patent, which is to confer a lawful monopoly on its holder." The policy implications are bleak regarding benefits to the consumer:

> The irony of all this is that the majority's decision may very well discourage generics from challenging pharmaceutical patents in the first place. Patent litigation is costly, time consuming, and uncertain. . . . Taking the prospect of settlements off the table—or limiting settlements to an earlier entry date for the generic [] puts a damper on the generic's expected value going into litigation, and decreases its incentive to sue in the first place. The majority assures us, with no support, that everything will be okay because the parties can settle by simply negotiating an earlier entry date for the generic drug manufacturer, rather than settling with money. . . . But it's a matter of common sense, confirmed by experience, that parties are more likely to settle when they have a broader set of valuable things to trade. (citations omitted).

V. CONCLUSION

The Court's decision will likely end reverse payment settlement agreements, making generic competition less likely. Unable to settle, innovator patentees will litigate every case to conclusion—to avoid antitrust scrutiny involving the same or similar infringement and validity questions better settled in ANDA litigation. There is now little advantage for either party in an ANDA lawsuit to settle and thus incur greater costs and risk that should deter rather than incentive generic challenges.

[8] *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries*, Inc., 508 U. S. 49, 60–61 (1993).

And while is not the likely consequence that the majority envisioned, it is almost certainly the outcome that will result from this decision.