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I. INTRODUCTION

The Eleventh Circuit's recent decision in *Federal Trade Commission v. Watson Pharmaceuticals, Inc.*[2] (the "*AndroGel*" decision) addresses the latest challenge to reverse-payment settlements. The Eleventh Circuit rejected the Federal Trade Commission's ("FTC") position that the lawfulness of a reverse-payment settlement depends on the perceived strength or weakness of the patent and concluded that a patent, unless previously invalidated, should be given its full exclusionary scope.

II. BACKGROUND

The *AndroGel* case involves a settlement agreement between Solvay Pharmaceuticals, Inc. ("Solvay"), the holder of a patent for a brand-name drug called AndroGel, and generic producers, Watson Pharmaceuticals, Inc. ("Watson"), and Paddock Laboratories, Inc. ("Paddock"). Paddock later collaborated with Par Pharmaceutical Companies, Inc. ("Par"), in a litigation cost-sharing arrangement (taken together, "Par/Paddock"). Both Watson and Paddock developed generic versions of AndroGel and filed Abbreviated New Drug Applications with "Paragraph IV" certifications.

In response, Solvay filed a patent infringement suit against the generic manufacturers. After several years of litigation and while motions for summary judgment were pending, the parties agreed to settle their dispute.

The settlement agreements allegedly included, among other terms, "reverse" payments by the patent holder, Solvay, to the asserted infringers, Watson and Par/Paddock, respectively. The settlements also included commitments by the generic manufacturers not to market generic AndroGel until 2015, five years prior to the expiration of the Solvay patent.

III. THE FTC'S POSITION

Soon after the settlements took effect, the FTC filed an antitrust complaint against Solvay, Watson, and Par/Paddock alleging that the settlements were "unlawful agreements not to

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[2] 677 F.3d 1298 (11th Cir. 2012).

compete in violation of Section 5(a) of the Federal Trade Commission Act."[3] The FTC claimed that the generic challengers had "developed persuasive arguments and amassed substantial evidence that their generic products did not infringe the [] patent and that the patent was invalid and/or unenforceable."[4] The FTC argued that, "because the [] patent 'was unlikely to prevent generic entry,' Solvay's reverse payments to the generic drug producers continued and extended a monopoly that the patent laws did not authorize."[5] As a result, the reverse payment settlements "unlawfully restrain[ed] competition."[6]

The defendant pharmaceutical companies moved to dismiss the complaint on the basis that the FTC did not allege that the settlements exceeded the scope of the underlying patent. In responding to the motion to dismiss, the FTC claimed that, based on the procedural posture and substantive record of the underlying patent-infringement case, Solvay was "not likely to prevail" in its patent-infringement litigation, and, as such, the patent conferred no right to exclude competition:[7]

> 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. And if the patent has no exclusionary potential, the FTC continues, then any reverse payment settlement that excludes any competition from the market necessarily exceeds the potential exclusionary scope of the patent and must be seen as the patent holder's illegal "'buying off' of a serious threat to competition."[8]

In effect, the FTC argued that courts should weigh the strength of the patent, as developed in the underlying patent-infringement litigation, to determine whether the settlement terms were within the exclusionary scope of the patent:

> [T]he FTC urges us 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." Under that rule, the FTC's allegation that Solvay was "not likely to prevail" in the patent litigation would state a plausible antitrust claim.[9]

According to the FTC, the existence of the reverse payment in this case rendered the settlement "inherently suspect" because that payment provided the "strong economic incentive" for the generic manufacturers to drop legitimate patent challenges in exchange for a share of the patent holder's monopoly profits.[10]

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[3] *Id*. at 1305; 15 U.S.C. § 45(a)(1).

[4] *AndroGel*, 677 F.3d at 1305-06.

[5] *Id*. at 1306.

[6] *Id.*

[7] *Id*. at 1312.

[8] *Id.* (emphasis in original).

[9] *Id*.

[10] *Id*. at 1301 ("Monopoly profits, the FTC says, will typically exceed the sum of the individual profits that the drug companies could make by competing against each other."); *see also* Petition for Rehearing En Banc of Federal Trade Commission at 7, 12-15, FTC v. Watson Pharmaceuticals, Inc. (3d Cir. June 11, 2012) (No. 10-12729-DD).

The FTC did not claim that the patent-infringement litigation was sham or that the relevant patent had been fraudulently obtained.[11] Rather, the FTC isolated the question of law as to whether the strength of the patent affected the legality of the settlement of the patent-infringement litigation where the settlement allegedly included a reverse payment.

The district court dismissed the FTC's complaint, finding that Solvay had the right to exclude others from entering the market to the full extent of the scope of its patent.

IV. ANDROGEL'S RELIANCE ON ELEVENTH CIRCUIT PRECEDENT

On appeal, the Eleventh Circuit rejected the FTC's reasoning that the lawfulness of a settlement depends on the perceived strength or weakness of the patent and affirmed the dismissal of the complaint. In doing so, the court reviewed its prior reverse-payment decisions, *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*,[12] *Schering-Plough Corp. v. Federal Trade Commission*,[13] and *Andrx Pharmaceuticals Inc. v. Elan Corp.*,[14] and determined that the holdings in those cases effectively resolved the *AndroGel* appeal.

The *AndroGel* court started its review by observing that the presence of a patent makes "all the difference" in determining the legality of reverse-payment agreements:

> Our *Valley Drug* decision began by acknowledging that antitrust laws typically prohibit agreements where one company pays a potential competitor not to enter the market, but we reasoned that reverse payment settlements of patent litigation presented atypical cases because "one of the parties own[s] a patent." The patent made all the difference because it meant that the patent holder had a "lawful right to exclude others" from the market. [15]

AndroGel further observed that the reverse-payment agreements at issue in *Valley Drug* did not constitute a *per se* antitrust violation "[b]ecause one party to the . . . agreements held a patent," and the agreements, therefore, "did not necessarily decrease the level of competition in the market."[16]

The plaintiffs in *Valley Drug*, however, contended that the patent was irrelevant to the antitrust analysis because it was invalidated by a court after the parties entered into their settlement agreement.[17] The *AndroGel* court noted that the plaintiffs in *Valley Drug* argued "that post-settlement invalidation meant the patent holder 'never had any patent rights,' which meant the settlements necessarily excluded more competition from the market than the patent holder was lawfully entitled to exclude (namely, none)."[18]

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[11] *Id.* at 1312 n.10.
[12] 344 F.3d 1294 (11th Cir. 2003).
[13] 402 F.3d 1056 (11th Cir. 2005).
[14] 421 F.3d 1227 (11th Cir. 2005).
[15] *AndroGel*, 677 F.3d at 1307 (quoting *Valley Drug*, 344 F.3d at 1304).
[16] *Id.* (citing *Valley Drug*, 344 F.3d at 1309); *see also Valley Drug*, 344 F.3d at 1309. ("If Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit.")
[17] *Valley Drug*, 344 F.3d at 1306-07; *see also AndroGel*, 677 F.3d at 1308.
[18] *AndroGel*, 677 F.3d at 1308 (quoting *Valley Drug*, 344 F.3d at 1306-07); *Valley Drug*, 344 F.3d at 1306-09.

The *Valley Drug* court rejected the plaintiffs' contention and clarified that the "mere subsequent invalidity of the patent does not render the patent irrelevant to the appropriate antitrust analysis."[19] Rather, as the *AndroGel* court explained, the relevant consideration is the patent's *potential* exclusionary power at the time of settlement.[20] A patent has the potential to exclude competition at settlement if it has not expired and has not been declared invalid by a court.[21] The actual exclusionary power of the patent is irrelevant if judged after the settlement takes effect. The court thus held that, even though the patent "was in fact invalid, its terms had to be given full effect"[22] because, at the time of settlement, "no court had declared [the] patent invalid."[23]

After reviewing *Valley Drug*, *Schering-Plough*, and *Andrx*, the *AndroGel* court articulated the rule of law to be applied to reverse-payment settlements: "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."[24] The court framed the issue in *AndroGel* as "whether, under that test, the FTC's complaint states an antitrust claim by alleging that Solvay was 'not likely to prevail' in the underlying infringement action . . . ."[25]

V. REJECTING THE "STRENGTH" OF THE PATENT AS A CRITERION FOR SETTLEMENT LEGALITY

The *AndroGel* court resolved the issue on appeal by holding that the settlements were immune from antitrust attack because Solvay had the right to exclude others from entering the market to the full extent of the scope of the patent. At the time the settlement agreements took effect, Solvay's patent was valid and restricted generic competition until 2020. The settlement terms excluded competition only until 2015, five years prior to the patent's expiration, and otherwise appeared to be within the scope of the patent.

The court "decline[d] the FTC's invitation" to weigh the likelihood that the patent would have "blocked generic entry earlier than the agreed-upon entry date."[26] Rather, the Eleventh

[19] *Valley Drug*, 344 F.3d at 1306-07; *see also AndroGel*, 677 F.3d at 1308.

[20] *AndroGel*, 677 F.3d at 1308; *see also Valley Drug*, 344 F.3d at 1306-07, 1309, 1311.

[21] *AndroGel*, 677 F.3d at 1308; *see also Valley Drug*, 344 F.3d at 1306-07, 1309, 1311. A court may find that a patent has the potential to exclude competition even after a court has adjudged the patent to be invalid if an appeal of that judgment is pending. For example, the Second Circuit has upheld a patent settlement agreement even where the parties settled after a district court holding that the underlying patent was invalid. *See In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 193, 220 (2d Cir. 2006). The settlement took effect while an appeal of the district court decision was pending before the Federal Circuit. Upon reaching the settlement agreement and before the Federal Circuit decided the appeal, the parties filed a "Joint Motion to Dismiss the Appeal as Moot and Vacate the Judgment Below." The Federal Circuit granted the motion, which vacated "the district court's judgment that the patent was invalid." *Id*. at 194.

[22] *AndroGel*, 677 F.3d at 1308.

[23] *Id*. (quoting *Valley Drug*, 344 F.3d at 1306) ("Because the patent had that potential at the time of settlement, we treated the holder as though it had an exclusionary right at that time.").

[24] *Id*. at 1312.

[25] *Id.*

[26] *Id*.

Circuit found the likelihood of Solvay's success in the underlying patent litigation legally irrelevant.

The court explained that Eleventh Circuit precedent "focus[es] on the potential exclusionary effect of the patent, not the likely exclusionary effect."[27] Probabilities of success at the time of settlement are irrelevant because "[o]ne side or the other almost always has a better chance of prevailing, but a chance is only a chance, not a certainty:"[28]

> The FTC's position equates a likely result (failure of an infringement claim) with an actual result, but it is simply not true that an infringement claim that is "likely" to fail actually will fail. "Likely" means more likely than not, and that includes a 51% chance of a result one way against a 49% chance of a result the other way. Giving the word its plain meaning, as many as 49 out of 100 times that an infringement claim is "likely" to fail it actually will succeed and keep the competitor out of the market.[29]

Regardless of one's perceived likelihood of success in litigation, strong incentives to settle remain:

> Rational parties settle to cap the cost of litigation and to avoid the chance of losing. Those motives exist not only for the side that is likely to lose but also for the side that is likely, but only likely, to win. A party likely to win might not want to play the odds for the same reason that one likely to survive a game of Russian roulette might not want to take a turn. With four chambers of a seven-chamber revolver unloaded, a party pulling the trigger is likely (57% to 43%) to survive, but the undertaking is still one that can lead to undertaking.[30]

AndroGel also reiterated that "the size of the payment[, or the mere presence of the payment,] should not dictate the availability of a settlement remedy."[31] Drug companies face "high risks and costs if they continue[] to litigate [an] infringement action."[32] As such, "even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in a settlement."[33]

The court cited other reasons to reject the FTC's "likely-to-prevail" approach. For example, the FTC's reasoning would "require an after-the-fact calculation of how 'likely' a patent holder was to succeed in a settled lawsuit if it had not been settled."[34] Yet predicting the outcome of any litigation is speculative and cannot serve as a rule of law:

> Predicting the future is precarious at best; retroactively predicting from a past perspective a future that never occurred is even more perilous. And it is too perilous an enterprise to serve as a basis for antitrust liability and treble damages . . . ; *cf. Whitmore v. Arkansas*, 495 U.S. 149, 159-60, 110 S. Ct. 1717,

[27] *Id.* at 1312-13.
[28] *Id.* at 1313.
[29] *Id.* at 1312 (internal citations omitted).
[30] *Id.* at 1313.
[31] *Id.* at 1310 (citing *Schering-Plough*, 402 F.3d at 1075).
[32] *Id.* at 1311 (citing *Schering-Plough*, 402 F.3d at 1073-75).
[33] *Id.* at 1313 (citing *Valley Drug*, 344 F.3d at 1310).
[34] *Id.* at 1313.

> 1725, 109 L. Ed. 2d 135 (1990) ("It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case.").[35]

The FTC's proposed rule would also undermine the primary benefits of settlement by "impos[ing] heavy burdens on the parties and courts:"[36]

> The FTC's retrospective predict-the-likely-outcome-that-never-came approach ... would require, in the FTC's words, "viewing the situation objectively as of the time of the settlement." In this case, assaying the infringement claim "as of the time of settlement" would have required mining through mountains of evidence—when the lawsuit settled, more than 40 depositions had been taken and one side alone had produced more than 350,000 pages of documents. The settlement made that unnecessary, but the FTC's approach would put that burden back on the parties and the court, undo much of the benefit of settling patent litigation, and discourage settlements. Our legal system can ill afford that.[37]

The closing sentiments of the court underscore that the perceived strength of the patent is irrelevant to the analysis of the legality of reverse-payment settlements:

> [W]hat the FTC proposes is that we attempt 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. If we did that we would be deciding a patent case[38] within an antitrust case about the settlement of the patent case, a turducken task.[39]

VI. NEXT STEPS IN THE ASSESSMENT OF REVERSE-PAYMENT SETTLEMENTS

The FTC's challenge of reverse-payment settlements in *AndroGel* is not over, as the FTC has filed a petition for rehearing *en banc*. In its petition, the FTC restates its position that reverse-payment settlements are "inherently suspect" and should be treated as presumptively unlawful. Specifically, the FTC argues that the *AndroGel* ruling allows holders of "very weak patent[s]" to induce generic competitors to stay out of the market in contravention of patent and antitrust law.[40]

According to the FTC, the *AndroGel* decision "upsets the balance between patent law and antitrust law":[41]

> [T]he Supreme Court [has] refus[ed] to exempt patent agreements [and settlements] from antitrust scrutiny . . . . Furthermore, the rule allows weak patents to stifle competition, which conflicts with patent law's encouragement of challenges to such patents . . . and with the Hatch-Waxman Act's goal of promoting generic entry specifically by rewarding those who challenge branded

[35] *Id.* at 1313-14 (internal citations partially omitted).

[36] *Id.* at 1314.

[37] *Id.*

[38] Elsewhere in the decision, the court observed that the resolution of patent appeals is within the exclusive purview of the Court of Appeals for the Federal Circuit. The court acknowledged that "other non-specialized circuit courts have no expertise or experience" in such matters. *Id.* at 1314-15.

[39] *Id.* at 1315.

[40] Petition for Rehearing En Banc of Federal Trade Commission at 1-2.

[41] *Id.*

> patents. Thus, with no justification from patent law, and contrary to the explicit goal of the Hatch-Waxman Act, the panel's rule puts the law of this Circuit into conflict with principles underlying antitrust law that prohibit a potential competitor from agreeing not to enter a market.[42]

The FTC concludes its petition by arguing that reverse-payment agreements appear similar to market-allocation agreements:

> Payments that, on their face, appear to be in exchange for market exclusion are similar to the agreements the Supreme Court condemned as per se unlawful in [*Palmer v. BRG of Georgia*, 498 U.S. 46 (1990)]. They thus bear a "close family resemblance [to] another practice that already stands convicted in the court of consumer welfare," and can properly be treated as "inherently suspect." *Polygram Holding, Inc. v. FTC*, 416 F.3d 29, 36-37 (D.C. Cir. 2005); see *N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346, 361 (5th Cir. 2008). "If structural evidence makes the practice look suspicious," the law should "force the defendant to show why it should be exonerated." Herbert Hovenkamp, The Antitrust Enterprise: Principle and Execution 146 (2005).[43]

Whether the legality of reverse-payment settlements will be definitively resolved in the near future remains an open question. To date, the Supreme Court has denied *certiorari* petitions on the issue,[44] and Congress has yet to legislate on the lawfulness of reverse-payment settlements.[45] The Third Circuit is expected to address reverse-payment settlements in the *K-Dur* potassium-medication case.[46] Until resolution arrives, the FTC continues to review new pharmaceutical settlements pursuant to the Medicare Modernization Act[47] and firmly holds its position against reverse-payment settlements.

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[42] *Id.* (internal citations omitted).

[43] Petition for Rehearing En Banc of Federal Trade Commission at 13-14.

[44] La. Wholesale Drug Co. v. Bayer AG, 131 S. Ct. 1606 (2011); *In re* Tamoxifen Citrate Antitrust Litig., *sub nom. Joblove v. Barr Labs. Inc.*, 127 S. Ct. 3001 (2007); FTC v. Schering-Plough Corp., 548 U.S. 919 (2006).

[45] Protecting Consumer Access to Generic Drugs Act of 2012 H.R. 3995, 112th Cong. (2011-2012); Preserve Access to Affordable Generics Act, S. 27, 112th Cong. (2011-2012).

[46] Plaintiff's Notice of Appeal, *In re* K-Dur Antitrust Litig. (3d Cir. 2010). The case was argued on December 12, 2011. A decision from the court is pending.

[47] *See* Medicare Modernization Act § 1112(a)(2).