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I. INTRODUCTION

The Federal Trade Commission ("FTC") in recent years has identified a practice it considers to be a threat to consumers regarding generic drugs. This threat is posed by the practice of "reverse payments" in ANDA litigation. Typically, in these arrangements a branded drug manufacturer settles litigation with a generic challenger brought under the Hatch-Waxman Act[2] and such settlements often involve a payment from the branded to the generic drug maker.

In the FTC's view, such payments should be illegal as anticompetitive market behavior amounting to a restraint on trade and a violation of the antitrust laws. However, despite judicial, legislative, and administrative attempts to ban the practice, neither Congress nor the courts have been willing to do so. While a ban on what the FTC characterizes as "pay for delay" practices have been a part of the Obama administration's budgets for the past few years, nothing has come of it.

II. BASIS FOR THE FTC'S REASONING

The FTC's reasoning and the basis for its crusade against such practices include the following:

1. First, generic competition decreases the costs of drugs to consumers and, more importantly, to the Federal government, the largest drug purchaser in the country if not the world.
2. Second, generic drug companies are motivated under the Hatch-Waxman Act to challenge patents, because the "first to file" an Abbreviated New Drug Application ("ANDA") with a certification that the generic product that does not infringe or, more commonly, that the innovator's patents are invalid or unenforceable, will garner a 180-day exclusivity period as the only generic on the market.

These two pillars of the FTC's reasoning are sound; indeed, one of the signal benefits of the Hatch-Waxman regime over the past twenty-eight years has been to increase the availability of generic drugs, often before they would have otherwise become available.

3. The third portion of the FTC's argument is that reverse payment agreements upset the statutory arrangement, permitting "bad" patents to remain in effect and delaying generic entry.

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[2] 35 U.S.C. § 271(e)(2)

4. Finally, the FTC contends that branded drug companies enter into reverse payment arrangements because they know that their patents are invalid and/or unenforceable and the agreement permit them to undeservedly collect "monopoly" prices.

This latter point is where the FTC's reasoning begins to go astray, because courts have found generally that reverse payment arrangements *reduce* the delay in generic entry. Indeed, courts have almost universally rejected the FTC's contention.[3] And, in the single instance, where a court *did* find a reverse payment agreement to be anticompetitive and an antitrust violation, the particular facts in that case established that the reverse payment was illegal.[4]

III. THE *WATSON* CASE

A. The Facts Behind the Case

More recently, the FTC's position was again rejected, in *Federal Trade Commission v. Watson Pharmaceuticals, Inc. et al.*[5] (the "et al." including the ANDA filer, Paddock Pharmaceuticals and its licensee, Par Pharmaceuticals). The case involved a reverse payment settlement between NDA holder Solvay Pharmaceuticals and ANDA filers Watson Pharmaceuticals and Paddock Pharmaceuticals over AndroGel, a prescription testosterone formulation prescribed for treating hypogonadism. Unimed (acquired by Solvay and later acquired by Abbott) and Besins Healthcare S.A. held the NDA, as well as Orange Book-listed U.S. Patent No. 6,503,894 ("the '894 patent") directed to the formulation; this patent will expire in August 2020.

Watson and Paddock filed separate ANDAs having Paragraph IV certifications that the '894 patent was invalid or unenforceable, and Unimed/Besins timely filed suit in the U.S. District Court for the Northern District of Georgia. The lawsuit was pending longer than the 30-month stay of ANDA approval specified in the statute,[6] and the FDA approved Watson's ANDA before the court could decide whether the '894 patent was invalid or unenforceable (neither Watson nor Paddock alleged that their products did not infringe the '894 patent). The parties settled the lawsuit before the Court ruled on the defendants' summary judgment motions of invalidity. As part of the settlement, the District Court entered a Stipulation of Dismissal against Watson and a permanent injunction against Paddock.

In addition to these actions by the District Court, the parties agreed that the defendants 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 Unimed's (later Solvay's) AndroGel product until the agreed time for their own product launch, and that Unimed (later Solvay) would pay the parties (approximately $20-30 million to Watson, approximately $10 million to Par/Paddock) annually.

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[3] *See Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003); *Schering-Plough Corp. v. Federal Trade Commission*, 402 F.3d 1056 (11th Cir. 2005); *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006), *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 105 (2d Cir. 2010); and *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008).

[4] *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003)

[5] *Federal Trade Commission v. Watson Pharmaceuticals, Inc,* 677 F.3d 1298 (11th Cir. 2012) ("Androgel").

[6] 35 U.S.C. § 271(e)(2)

In addition, Par/Paddock agreed to supply AndroGel to Unimed (later Solvay) in a "backup capacity" for an additional $2 million annually.

The FTC investigated these settlement agreements pursuant to a provision of the law enacted in part as result of the FTCs concern over the practice of reverse payments in ANDA litigation settlements.[7] As a result of its investigation, the FTC alleged violations of Section 5a of the Federal Trade Commission Act.[8] The case was originally brought in the Central District of California but was transferred to the Northern District of Georgia, where the District Court granted defendants' motion to dismiss for failure to state a claim.[9]

B. The District Court's Rejection of the FTC's Contentions

In granting the defendants' motion, the District Court rejected the FTC's contentions: "(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 to AndroGel and thereby monopolizing the market."

The basis for the District Court's dismissal was that, in the 11th Circuit, reverse payments did not constitute anticompetitive behavior so long as the terms of the settlement remain within the scope of the 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.

C. The 11th Circuit Affirms

The 11th Circuit affirmed, in an opinion by Judge Carnes joined by Circuit Judge Kravitch and 9th Circuit Court Judge Farris (sitting by designation) and applying the 11th Circuit standard of *de novo* review of granted motions to dismiss.

The opinion from the outset showed little patience with the FTC's theories, saying that new drugs are produced in the United States under the maxims "no risk, no reward" and "more risk, more reward," and that "no rational actor" (the economists' archetype) "would take [the] risk" of investing more than "$1.3 billion" on a potential drug where "[o]nly one of every 5,000 medicines tested . . . is eventually approved for patient use" "without the prospect of a big reward." Under this system, the Court recognized that the successful drug maker who patents its drug will "usually[] recoup its investment and make a profit, sometimes a super-sized one."

The Court also noted that "more money, more problems" is often the result, with the profits "frequently attract[ing] competitors in the form of generic drug manufacturers that challenge or try to circumvent the pioneer's monopoly in the market." The Court recognized as the "key allegation in the FTC's complaint" that "the patent holder [is] 'not likely to prevail' in the patent infringement action" that arises in the Hatch-Waxman context. The Court also recognized the FTC's position that reverse payments are *per se* anticompetitive that constitute "unlawful

[7] 21 U.S.C. § 355 note (2003)
[8] 15 U.S.C. § 45(a)(1).
[9] Fed. R. Civ. Pro. 12(b)(6); *In re AndroGel Antitrust Litigation*, 687 F.Supp.2d 1371 (N.D. Ga. 2010)

restraints on trade" and hence violations of Section 1 of the Sherman Act, and cited (albeit in a footnote) the economic rationale advanced by the FTC in this and other contexts:

> According to a study conducted by the FTC of the industry as a whole . . ., a branded manufacturer typically loses about 90 percent of its unit sales over the course of generic entry. While generic entrants gain that unit volume, they do not gain all the revenues lost by the branded manufacturer because, as generic competition sets in, the price falls, on average, to about 15 percent of what the branded manufacturer was charging. Thus, a branded manufacturer can expect that, if a drug is earning $1 billion a year before generic entry, the manufacturer will only earn about $100 million a year once generic competition has matured, and all the generic companies put together will only earn about $135 million a year (90% x 15% x $1 billion), thus leaving approximately $765 million a year for the public through the benefits of competition. The parties have a strong economic incentive to avoid that result.[10]

The Court in its opinion also acknowledged that "Federal law encourages generic drug manufacturers to file paragraph IV certifications."

D. The Importance of Owning a Patent

Because the FTC's complaint was dismissed, all factual allegations in the complaint were accepted as true. In its analysis of the legal basis for the FTC's allegations, the Court stated that "[t]he lynchpin of the FTC's complaint is its allegation that Solvay probably would have lost the underlying patent infringement action" and that "Solvay was not likely to prevail" in the patent litigation because "Watson and Par/Paddock developed persuasive arguments and amassed substantial evidence that their generic products did not infringe the ['894] patent and that the patent was invalid and/or unenforceable" (emphasis in original). "The difficulty," according to the Court, "is [in] deciding how to resolve the tension between the pro-exclusivity tenets of patent law and the pro-competition tenets of antitrust law," a difficulty that "is made less difficult [] by the law's proprecedent tenets" and "[o]ur earlier decisions" which "carry us much of the way to a resolution of [the] case."

The Court addressed this task by reviewing 11th Circuit precedent, all of which reject the FTC's position, and discussed the bases for these earlier decisions. While noting that generally agreements between competitors that keep one competitor from the market to the benefit of the other (and that increase costs to the public) would be barred under the antitrust laws, reverse payment cases were "atypical cases because 'one of the parties [owns] a patent'," citing *Valley Drug*. This "makes all the difference," according to the opinion, because the patent holder "has a lawful right to exclude others" from the marketplace. Said another way, "[t]he anticompetitive effect is already present" due to the existence of a patent," citing *Schering Plough.*

Further citing *Valley Drug*, the Court said that even subsequent invalidation of the patent would not render the agreement unlawful, since its lawfulness must be considered at the time of settlement, where the patentee "had the right to exclude others." What counts is the "potential exclusionary power" of the patent at the time of the reverse payment settlement, not its "actual exclusionary power" *unless* a court had rendered a negative judgment of invalidity or unenforceability prior to the settlement (an unlikely but not impossible scenario).

[10] *Federal Trade Commission v. Watson Pharmaceuticals, Inc,* 677 F.3d 1298 at fn.2

The Court noted that the mere existence of a patent did not give the parties to a reverse payment settlement *carte blanche*, because any such settlement cannot "exclude[] more competition that the patent has the potential to exclude." This reverse payment agreements remain "vulnerable to antitrust attack" (on a case-by-case basis) according to the opinion, and are subject to a "three-prong analysis" that requires an evaluation of: "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects," citing *Valley Drug*.

In a footnote, the Court also clarified the meaning of the term "strength of the patent" as used in the *Schering Plough* case:

> The FTC's brief in this case places great weight on our statement in Schering-Plough that a proper antitrust analysis of reverse payment agreements needs to "evaluate the strength of the patent." 402 F.3d at 1076 (emphasis added). The FTC argues that evaluating the "strength of the patent" means evaluating "the strength of the patent holder's claims of validity and infringement, as objectively viewed at the time of settlement." We disagree. When read in the context of the facts and the reasoning of Schering-Plough, the phrase "strength of the patent" refers to the potential exclusionary scope of the patent—that is, the exclusionary rights appearing on the patent's face and not the underlying merits of the infringement claim. Nowhere in the Schering-Plough opinion did we actually evaluate the merits of the infringement claim when defining how much competition the patent could potentially exclude from the market.[11]

E. Determining When a Reverse Payment Settlement is Immune from Antitrust Attack

The Court also provided useful contrast between these earlier cases denying antitrust liability with one, *Andrx Pharmaceuticals, Inc. v. Elan Corp.*,[12] in which the Court reversed dismissal of an antitrust case brought by a private party. In that case, the generic drug maker "had agreed 'to refrain from ever marketing a generic' version of the patented drug," and the generic drug maker was permitted to "retain its 180 day exclusivity period" despite having "no intention of marketing the drug." This resulted in the generic drug maker's 180-day exclusivity period to "act[] like a cork in a bottle" preventing another generic drug maker from entering the market. (This tactic was eliminated by later amendments to the statute wherein the first ANDA filer can forfeit its exclusivity rights if it fails to market a generic version of a patented drug "within certain time periods."[13]).

The Court then synthesized the rule from these cases: "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 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 "no exclusionary potential" (emphasis in original); and (3) if a patent has no exclusionary potential, the reverse payment arrangement "necessarily" exceeds its

[11] *Federal Trade Commission v. Watson Pharmaceuticals, Inc,* 677 F.3d 1298 at fn.8

[12] 421 F.3d 1227 (11th Cir. 2005)

[13] 21 U.S.C. § 355(j)(5)(D)

"potential exclusionary scope" and thus is tantamount to "'buying off' a serious threat to competition."

According to the opinion, the FTC was urging the Court "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 Court "decline[d] the FTC's invitation and reject[ed] its argument," saying that to adopt either would "equate[] a likely result (failure of an infringement claim) with an actual result."

In this context, according to the Court, if Solvay was "likely" to fail to survive litigation that meant its chances for failure vs. success could actually be almost equal, with failure being 51 percent and success being 49 percent. Under these circumstances "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." Under these circumstances the Court reasoned that "rational parties settle to cap the cost of litigation and to avoid the chance of losing," noting that "[o]ne side or the other almost always has a better chance of prevailing, but a chance is only a chance, not a certainty."

The rationality, rather than possible perfidity, of this behavior was illustrated colorfully as follows:

> 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.

Patent litigation is analogous, according to the opinion, and "[w]hen both sides of a dispute have a substantial chance of winning and losing, especially when their chances may be 49% to 51%, it is reasonable for them to settle" without incurring antitrust liability for doing so. The Court continues its theme of the rationality of this behavior, citing *In re Ciprofloxacin Hydrochloride Antitrust Litigation*:[14]

> No matter how valid a patent is—no matter how often it has been upheld in other litigation or successfully reexamined—it is still a gamble to place a technology case in the hands of a lay judge or jury. Even the confident patent owner knows that the chances of prevailing in patent litigation rarely exceed seventy percent. Thus, there are risks involved even in that rare case with great prospects.

F. Practical Difficulties With the FTC's Approach

In addition, the Court noted practical difficulties with the FTC's approach, including "an after-the-fact calculation of how 'likely' a patent holder was to succeed in a settled lawsuit if it had not been settled," calling it a "retrospective predict-the-likely-outcome-that-never-came approach" and that "[p]redicting 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." The Court also emphasized the burden on the parties and courts in this approach, noting that it would

[14] 261 F. Supp. 2d 188, 208 (E.D.N.Y. 2003)

discourage settlements against the general consensus that settlements of litigation should be encouraged.

The Court also noted that the FTC itself had voiced concerns over the approach now espoused in appeal:

> An after-the-fact inquiry by the Commission into the merits of the underlying litigation is not only unlikely to be particularly helpful, but also likely to be unreliable. As a general matter, tribunals decide patent issues in the context of a true adversary proceeding, and their opinions are informed by the arguments of opposing counsel. Once a case settles, however, the interests of the formerly contending parties are aligned. A generic competitor that has agreed to delay its entry no longer has an incentive to attack vigorously the validity of the patent in issue or a claim of infringement. *In re Schering-Plough Corp.*[15]

The Court suggested that the FTC's pattern of filing suit in the various regional circuit courts of appeal is inconsistent with the Congressional mandate that the Federal Circuit hear appeals of patent cases exclusively. (The Federal Circuit has followed the 11th Circuit's reasoning in reverse payment cases.) And the FTC's concerns are likely to be overstated, according to the Court, because of "the reality that there usually are many potential challengers to a patent, at least to drug patents" and other generic competitors will arise to challenge the patent. If the FTC is correct that reverse payment arrangements indicate a "weak" or vulnerable patent, the "blood in the water" will likely provoke a "feeding frenzy" of other challenges:

> Although a patent holder may be able to escape the jaws of competition by sharing monopoly profits with the first one or two generic challengers, those profits will be eaten away as more and more generic companies enter the waters by filing their own paragraph IV certifications attacking the patent.

Finally, the Court also noted Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 25 (2004) for te proposition that, "[i]n a world in which there are numerous firms willing and able to enter the market, an exit payment to one particular infringement defendant need not have significant anticompetitive effects. If there is good reason for believing the patent [is] invalid others will try the same thing."

Regardless of these realities, it is unlikely that the FTC's crusade against reverse payment settlements will diminish.

[15] No. 9297, 2003 WL 22989651, at *22 (F.T.C. Dec. 8, 2003)