No. 10-12729-DD

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

FEDERAL TRADE COMMISSION,
Plaintiff-Appellant,
v.
WATSON PHARMACEUTICALS, INC., et al.,
Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
Case No. 1:09-cv-00955-TWT

REPLY BRIEF FOR PLAINTIFF-APPELLANT FEDERAL TRADE COMMISSION

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TABLE OF CONTENTS

PAGE

TABLE OF AUTHORITIES*

CASES **PAGE**

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MISCELLANEOUS

INTRODUCTION AND SUMMARY

The central question in this appeal is whether, under this Court's precedents, a settlement of a patent infringement action in which the patent holder pays a potential generic competitor to stay out of the market is immune from antitrust scrutiny so long as (1) the infringement action is not a sham, (2) the settlement only restricts products covered by the patent, and (3) the settlement restrictions do not extend beyond patent expiration. Defendants say yes, but their argument rests on a fundamental misconstruction of the first step of the analysis under this Court's precedents: evaluating a patent's exclusionary potential. Defendants, equate "exclusionary potential" with anything a patent holder could obtain if it prevailed in its infringement action, no matter how unlikely (short of sham) success was. Defendants' rule may be easy to apply, but it is at odds with this Court's decisions. Those decisions teach that the likelihood of the patent holder prevailing in its infringement action helps define the patent's potential exclusionary scope, and the size of payments relative to the profits the infringers could expect is relevant to assessing that likelihood. The Commission's complaint includes allegations regarding all these factors, and the district court erred when it granted defendants' Rule 12(b)(6) motion.

Defendants contend that, to promote pharmaceutical innovation, this Court's

rulings should be read as rendering such agreements virtually immune from antitrust challenge. But this would be inconsistent with (1) this Court's efforts to accommodate *both* patent and antitrust law, (2) Supreme Court precedent, and (3) the balance struck by the Hatch-Waxman Act, which seeks both to promote innovation and to encourage generic manufacturers to challenge patents. If this Court were to agree with defendants' reading of its prior rulings, then the Court should reconsider those decisions *en banc*.

Finally, Par/Paddock raise two arguments not addressed by the district court. They contend that, because the district court approved their settlement with Solvay, it is immune from antitrust scrutiny pursuant to the *Noerr* doctrine. But court approval cannot confer *Noerr* immunity because the court never saw or approved essential elements of the settlement. Par/Paddock also contend that their settlement did not violate the law because it caused no harm. However, the Commission's complaint alleges plausible harm, and such a factual dispute cannot be resolved on a 12(b)(6) motion.

I. THE DISTRICT COURT, AND DEFENDANTS, MISINTERPRET THIS COURT'S PRECEDENTS

Defendants equate a patent's exclusionary potential with the relief a patent holder could obtain if it prevailed in all aspects of its infringement litigation (so long as the litigation was not a sham). Defendants contend it is irrelevant that the

Commission alleged that Solvay was likely to have lost the two infringement challenges it brought, or that, in the absence of the substantial payments Solvay agreed to make, Watson, Par, and Paddock would not have agreed to defer marketing their generic products until 2015. According to defendants, a settlement exceeds the exclusionary potential of a patent only if it "provide[s] for exclusion going beyond the patent's term or operate[s] to exclude clearly noninfringing products * * *." Brief for Appellees Unimed Pharmaceuticals, LLC, Abbott Products, Inc., and Watson Pharmaceuticals, Inc. ("Watson Br.") at 15-16. Because the Commission's complaint did not contain such allegations, defendants contend the complaint must be dismissed. But that is not what this Court's decisions say.[1]

A. According to this Court's precedents, the likelihood that a patent holder will prevail in infringement litigation is relevant

This Court's three prior decisions addressing Hatch-Waxman settlements take a more nuanced approach than the one defendants advocate.

1. *Valley Drug*

In *Valley Drug Co. v. Geneva Pharms.*, 344 F.3d 1294 (11th Cir. 2003), the

[1] To avoid repetition, Part I focuses on the appropriate interpretation of the plain language of this Court's decisions. Part II discusses the reasons justifying this interpretation. These reasons not only lend further support to this interpretation, but also support *en banc* reconsideration if this Court disagrees with our understanding of its prior decisions.

district court initially held that agreements between a patentee (Abbott Laboratories) and two potential generic competitors were *per se* antitrust violations. This Court reversed, but did not, as defendants seem to believe, suggest that such agreements were somehow *per se* lawful. *See* Watson Br. at 23-29. Instead, it held that the agreements were not *per se* unlawful, and then explained how such agreements should be analyzed. To accommodate the policies of both the patent laws and the antitrust laws, this Court held that the district court should have first considered the scope of the exclusionary potential of the patent, and then should have assessed the extent to which the challenged agreements exceeded that scope. The court may then consider the anticompetitive effects of any provisions of the agreements. 344 F.3d at 1312. Factors that are relevant to assessing the exclusionary potential of the patent include the strength of the patent: "'some care must be taken to ensure that . . . the settlement . . . is not more anticompetitive than a likely outcome of the litigation.'" *Id.* at 1312, quoting 12 Herbert Hovenkamp, *Antitrust Law* ¶ 2046. Other factors include whether the size of the payments raised suspicion that Abbott "lacked faith in the validity of the patent," *id*. at 1309-10; the amount of profits Abbott expected to lose if it faced generic competitors, *id.* at 1310; and the structure of the payments, *id.*

On remand, the district court, following this Court's instructions, analyzed

the agreement that prohibited Geneva Pharmaceuticals from marketing its generic product pending the outcome of litigation regarding the validity of Abbott's patent.[2] *In re Terazosin Hydrochloride Antitrust Litigation*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005). First, the district court considered the exclusionary potential of the relevant patent. This "require[d] an analysis of the underlying patent litigation," including "an evaluation of the likely outcomes of the * * * patent litigation * * *." 352 F. Supp. 2d at 1295. The court also observed that it had to evaluate "whether the settlement represented a reasonable implementation of the protections afforded by the [relevant] patent, in light of the applicable law, the then-pending litigation, and the general policy justifications supporting settlements of intellectual property disputes." *Id.* at 1295-96. "The exclusionary value of the patent, therefore, cannot be defined by looking at the patent terms in a vacuum; instead, when litigation is pending as to the validity of the patent, the chances that the patent will be held valid must be considered as part of the analysis." *Id.* at 1296-97. "[A]ny construction of the patent's exclusionary scope * * * that fails to

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[2] Defendants mistakenly contend that this Court upheld one of the agreements that was at issue in *Valley Drug* (the agreement between Abbott and generic marketer Zenith Goldline Pharmaceuticals). *See* Watson Br. at 28, 44 n.16. In fact, antitrust charges regarding that agreement were resolved by settlement. *See In re Terazosin*, 352 F. Supp. 2d at 1286 n.3. Far from upholding either of the agreements at issue, all this Court actually held was that neither could be categorized as *per se* unlawful. 344 F.3d at 1306.

take into account the chances of the patent being held invalid would essentially afford pioneer drug manufacturers an unbridled power to exclude others without regard to the strength of their patent rights." *Id.* at 1298.

The court concluded that a portion of the agreement that provided that Geneva would not market its generic product pending ongoing litigation was akin to a preliminary injunction. Accordingly, it assessed "whether it was more likely than not that Abbott could have obtained a preliminary injunction * * * to keep Geneva off the market." *Id.* at 1301. The court then considered "the likelihood of Abbott prevailing on the merits of the * * * patent litigation, gauged as of the date on which the Agreement was entered into," *id.* at 1302, and it concluded that the patent would be found invalid, *id.* at 1307. Because the agreement was beyond the exclusionary potential of the patent, the court subjected it to antitrust analysis and concluded that it violated the Sherman Act. *Id.* at 1312-19.

2. *Schering*

In *Schering-Plough v. FTC*, 402 F.3d 1056 (11th Cir. 2005), this Court reviewed the Commission's fully litigated administrative decision. The Commission had analyzed two settlements between Schering and would-be generic challengers (Upsher and ESI), and concluded that both agreements violated the FTC Act's prohibition of unfair methods of competition. *In re Schering-Plough*

Corp., 136 F.T.C. 956 (2003). Reversing, this Court criticized the Commission for failing to consider either the exclusionary potential of Schering's patent, or the underlying merits of the patent dispute between Schering and the generic manufacturers. 402 F.3d at 1066-68 & n.18. Such considerations are necessary because "a delicate balance must be drawn between" the goals of the patent laws and the antitrust laws. *Id.* at 1067. This Court also held that the Commission had not shown that the agreements exceeded the exclusionary scope of the patent. With regard to the agreement with Upsher, this Court concluded that there was nothing in the record to show that the payments Schering agreed to pay to Upsher were not a fair price for a license that Upsher was granting to Schering (the license allowed Schering to market one of Upsher's products). *Id.* at 1071.

With regard to ESI, this Court held that the Commission had presented "relatively limited evidence" showing that this agreement was unreasonable. *Id.* Schering, however, had presented experts who testified that Schering would have won its infringement action against ESI, and that the entry date in the settlement "reasonably reflected the strength of Schering's case." *Id.* This Court faulted the Commission for "refus[ing] to consider the underlying patent litigation * * *," and thus concluded that the terms of the ESI settlement were within the scope of the patent's exclusionary power. *Id.* at 1702.

Finally, this Court observed that "parties settle cases based on their perceived risk of prevailing in and losing the litigation," *id.* at 1073, but the Commission had presented no evidence regarding that perceived risk. This Court also criticized the Commission for failing to provide evidence in support its holding that, in the absence of payments from Schering to the generics, the generics would have entered the market at an earlier date. In the absence of such evidence, this Court concluded that the settlements "fell well within the protections" of Schering's patent. *Id.* at 1076. "Simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law. This alone underscores the need to evaluate the strength of the patent." *Id.*

3. *Andrx*

This Court's most recent decision addressing exclusionary-payment settlements, *Andrx Pharms., Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005), is procedurally similar to this case. The district court granted a pre-trial motion dismissing Andrx's antitrust challenge of a settlement between brand-name drug manufacturer Elan and its potential generic competitor, SkyePharma. As part of that settlement, SkyePharma conceded its generic would violate Elan's patent, and received both monetary compensation and a license from Elan to market a generic

version of Elan's drug.

This Court reversed the dismissal. The Court held that Andrx had sufficiently alleged that the settlement exceeded the exclusionary scope of the patent. The scope of the patent's exclusionary potential should be assessed in light of whether the patent is "necessary" to the manufacture and sale of the generic, and whether the patent holder could "effectively exclude" potential competitors. 421 F.3d at 1235. In remanding the case for further proceedings, this Court recognized that cases such as the one brought by Andrx "are 'fact-intensive' * * * and therefore are typically inappropriate for a Rule 12 dismissal in the absence of an applicable immunity doctrine." *Id.* at 1236 (citations omitted).

B. Defendants misunderstand this Court's precedents

Defendants draw several lessons from this Court's cases, but get them all wrong.[3] First, defendants contend that payments to an accused infringer are irrelevant to any antitrust analysis. Watson Br. at 24. Although, in *Valley Drug*,

[3] Defendants are absolutely mistaken when they contend that "[t]he FTC's brief does not seriously argue that the settlements here are subject to antitrust scrutiny under this Court's existing precedents." *See* Watson Br. at 36. In fact, as explained above, that is exactly what the Commission argues. And there is no merit to defendants' contention that the Commission has "continuously shifted its position," *see* Watson Br. at 39 n.13. As argued in Part II, *infra*, the Comission's position remains that the best approach is to recognize that settlements with exclusion payments are presumptively unlawful. However, that this Court's precedents can and should be read as supporting liability under the approach advanced in this Part, and the allegations in the Commission's complaint are consistent with those precedents.

this Court rejected the notion that a payment was a dispositive factor, it nonetheless recognized that the size of a payment made to an alleged infringer may "raise[] the suspicion that the parties lacked faith in the validity of the patent."[4] 344 F.3d at 1309-10. Similarly, in *Schering*, this Court held that, "[s]imply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the *sole* basis for a violation of antitrust law. This alone underscores the need to evaluate the strength of the patent."[5] 402 F.3d at 1076 (emphasis added).

Accordingly, the payments that Solvay made in this case to Watson, Par, and Paddock are far from irrelevant. They may provide evidence regarding the parties' perception of the strength of Solvay's patent. In its complaint, the Commission alleged that, although Solvay's payments pursuant to the settlements were

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[4] Defendants quote this Court's statement that 'it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit." Watson Br. at 24, quoting *Valley Drug*, 344 F.3d at 1309. However, this merely indicates that payments to a potential generic competitor do not render a settlement agreement *per se* unlawful.

[5] Defendants note that, in *Schering*, this Court quoted from Judge Posner's decision in *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003), in which he observed that any settlement agreement could be characterized as involving a payment to the alleged infringer. 402 F.3d at 1074. From this, defendants conclude "[t]here is thus no meaningful limit to the FTC's proposed rule." *See* Watson Br. at 47. Although, in *Schering*, the Commission suggested that settlements involving payments to alleged infringers are normally unlawful, *see* 136 F.T.C. at 988, the Commission's principal argument in this case is not based on any such "rule." Instead, the Commission's complaint is consistent with the nuanced approach set forth in this Court's cases.

structured as payments for services, the amounts greatly exceeded the value of any services that Watson, Par, and Paddock agreed to provide.[6] Thus, the Commission alleged that the payments were not independent business transactions, but were tied to the parties' perception of the likelihood that Solvay's infringement actions would fail.[7] D.114 ¶¶ 81-85, 96. The Commission further alleged that, but for the payments, generic competition to Androgel would have occurred earlier than 2015. D.114 at ¶ 97. The Commission's complaint does not merely assume earlier generic entry; instead, it details evidence showing that the defendants expected that generic Androgel would be on the market prior to 2015, in the absence of payments. *See id.* at ¶¶ 57-59, Ex. A (describing and attaching a financial analysis that links Watson and Par/Paddock's delayed entry to the size of payments made by Solvay). *Compare Schering*, 402 F.3d at 1073 (criticizing the Commission for assuming earlier generic entry). The Commission is not seeking to "outlaw

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[6] In *Schering*, this Court faulted the Commission for failing to make a similar showing, *i.e.*, that the payments made by Schering to Upsher did not represent a fair price for the marketing rights Schering received. 402 F.3d at 1071. This Court explained that the presence of payments does not "dictate" the antitrust analysis, *id.* at 1075, but it never suggested, as defendants do, *see* Watson Br. at 40, that such payments are irrelevant to the analysis.

[7] Defendants claim that the payments to Watson, Par, and Paddock were "relatively small sums" compared to Solvay's annual sales of Androgel. Watson Br. at 13-14. However, the payments may have exceeded the profits that Watson, Par, and Paddock would have attained had they entered the market with generic versions of Androgel. *See* D.114 at ¶¶ 49-51; FTC Br. at 33-35.

settlement payments to infringers." *See* Watson Br. at 41. Instead, it seeks an opportunity to present evidence showing that Solvay's settlement agreements are illegal under the antitrust laws as interpreted by this Court. The district court's dismissal of the complaint denied the Commission this opportunity.

Defendants also mistakenly claim that this Court has held that, unless the Commission alleges that Solvay's infringement litigation was a sham, Solvay's likelihood of success in that litigation is irrelevant. Watson Br. at 24. In fact, this Court's opinions indicate that the likelihood that a patent holder will prevail in an infringement challenge is relevant to the scope of the exclusionary potential of the patent. In *Valley Drug*, this Court cautioned that, in a challenge of a settlement agreement, a court must take "some care" to make sure that the settlement is not more anticompetitive than the "likely outcome" of the litigation that the settlement resolves. 344 F.3d at 1312. And, following this Court's instructions, the district court on remand carefully evaluated what the outcome of the litigation would have been if the parties had not settled.[8] 352 F. Supp. 2d at 1296-7. Similarly, in *Schering*, this Court faulted the Commission for failing to present evidence

[8] Defendants note that, in its administrative decision in *Schering*, the Commission observed that, if the legality of a settlement depended upon the likelihood of success of the patent holder's infringement action, then parties entering into such settlements would be subject to serious uncertainties. Watson Br. at 39, citing *In re Schering*, 136 F.T.C. at 998. However, as explained above, this Court has made clear that the likelihood of success is relevant in an action such as this one.

regarding the underlying patent litigation, whereas Schering presented experts who testified that Schering would have prevailed. Moreover, it was relevant to this Court that, in Schering's settlement with ESI, the entry date "reflected the strength of Schering's case." 402 F.3d at 1071-72.[9] Accordingly, defendants are mistaken when they contend that *Schering* holds that evidence regarding the likely outcome of such litigation is irrelevant. Watson Br. at 25-26.

Evidence regarding the likely outcome of Solvay's litigation is relevant both to the strength of its patent, and to the extent to which the settlement exceeds the scope of the protection afforded by Solvay's patent. The Commission alleged that Solvay, Watson, Par, and Paddock all thought that it was likely that Solvay's infringement litigation would fail. D.114 ¶¶ 3, 48-56. The complaint included a number of reasons why. *See, e.g., id.* at ¶ 87 (the generic versions of Androgel included ingredients, or amounts of ingredients, not covered by Solvay's patent); ¶ 88 (the patent was invalid for prior commercial sale or public use); *id.* (the patent was invalid as obvious), etc. Thus, defendants are simply mistaken when they

[9] To support their contention that the Commission can prevail only if it shows that Solvay's infringement actions were a sham, defendants note that, in *Valley Drug*, this Court quoted from *Walker Process Equip., Inc. v. Food Machinery and Chem. Corp.*, 382 U.S. 172, 86 S. Ct. 347 (1965). Watson Br. at 25. But this Court quoted from *Walker Process* only to establish that, in a situation such as this one, the mere fact that a patent is subsequently declared invalid does not automatically expose the parties to antitrust liability.

contend that the Commission's complaint did not allege that the settlements exceeded the exclusionary potential of Solvay's patent. *See* Watson Br. at 32-36.

Accordingly, there is no merit to defendants' claim that "patent settlements do not violate the antitrust laws unless they contain provisions that * * * provide the patentee relief that it could not have obtained had it prevailed in its patent suit." *See* Watson Br. at 2, 26-29. They are also mistaken when they contend that, post-*Valley Drug*, "[e]very court to consider patent-settlement antitrust issues" has followed this principle. *See id.* at 3. As the district court's decision on remand in *Valley Drug* makes clear, it is not enough that the patentee *might* have stopped a generic competitor from entering the market pending litigation. What counts is whether it was likely to have obtained that result.[10] In that case, the district court evaluated a provision in the settlement pursuant to which Geneva agreed not to market its generic alternative pending final resolution of litigation regarding the

[10] Defendants contend that, on remand in *Valley Drug*, the district court "relied heavily" on the fact that the agreement at issue did not involve a final resolution of the patent dispute. Watson Br. at 27 n.7. This is incorrect. Instead, it merely considered this as one among a variety of factors relevant to whether the settlement was a reasonable implementation of the patent's protections. Notably, the court also observed that, despite the potential benefits of final settlements, "parties to an intellectual property dispute have a strong incentive to enter into agreements that maximize their own interests but disserve the public's interest with respect to either competition or innovation." 352 F. Supp. 2d at 1309 (internal quotation marks and citation omitted). In any event, as explained above, the primary focus of the court's analysis was the likelihood that Abbott would prevail in its patent litigation.

patent's validity. The district court concluded that the provision violated the antitrust laws. But if Abbott had prevailed in its patent litigation, it clearly could have prevented Geneva from marketing its generic drug during the 11-month period at issue. Thus, the district court's decision on remand in *Valley Drug* shows that the rule defendants propose is not the law of this Circuit.

Similarly, in *Schering*, if defendants were correct, this Court would not have found it relevant that Schering presented evidence regarding the likelihood that it would succeed in its infringement litigation against ESI. The only relevant issue would have been a simple one: did the settlement prohibit ESI from marketing its generic after the patent expired. Finally, in *Andrx*, this Court would not have stated that cases challenging settlements with generic manufacturers are "fact-intensive." Indeed, there is nothing "fact-intensive" about the rule defendants propose. The only issues would be the date the patent expires, and whether the generics at issue arguably infringe the patent.

Defendants contend that it would be difficult for courts to evaluate the likely outcome of infringement litigation, and that any analysis of the potential outcome would be unreliable.[11] Watson Br. at 53-57. However, on remand in *Valley Drug*,

[11] In *Valley Drug*, this Court stated that "[p]atent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages." Watson Br. at 42, quoting 344 F.3d at 1308. Defendants interpret this passage to mean that

the district court was able to evaluate both the likelihood that Abbott would be able to obtain a preliminary injunction to block Geneva from marketing generic terazosin pending the outcome of the litigation, 352 F. Supp. 2d at 1302-06, and the likely final outcome of the litigation, *id.* at 1306-07. Thus, a court can -- and must -- evaluate the likelihood of success in patent litigation.

In its complaint, the Commission alleged various reasons why Solvay was unlikely to prevail in its infringement litigation.[12] D.114 at ¶¶ 86-89. Although defendants complain that they might be required "to litigate in its entirety the very patent case they were trying to settle," *see* Watson Br. at 53, the Commission alleged that, at the time they entered into the settlements, defendants had completed all discovery and had filed summary judgment motions regarding

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the likely outcome of the infringement litigation is irrelevant to the antitrust analysis. But, read in context, the quoted passage implies that, even if the patent is subsequently held invalid, a previously entered settlement is not rendered *automatically* a violation of the antitrust laws.

[12] Defendants repeatedly quote from the reply brief that the Commission filed in support of its petition for *certiorari* in *Schering*. *E.g.*, Watson Br. at 53, 55, 57. They claim not to understand why, in that brief, the Commission argued that a court could find liability without evaluating the likely outcome of the parties' infringement litigation, but in this case the Commission has included allegations regarding that outcome. As the Commission explained in its reply in *Schering* (and in Part II of its opening brief in this case), it believes that exclusion payment settlements should be presumptively unlawful. But, as *Schering* makes clear, that is not the law in this Circuit. Accordingly, the Commission drafted its complaint with allegations sufficient to conform to the law of this Circuit.

several of the relevant issues, D.114 at ¶ 90. Thus, in this case, the parties to the settlements have already litigated the relevant issues, and there is no reason to believe that evaluation of the likely outcome of that litigation would be any more difficult, or any more "fact intensive," *see Andrx Pharms.*, 421 F.3d at 1236, than it was on remand in *Valley Drug*.[13]

Defendants contend that other courts have followed *Valley Drug* and *Schering*, and have held that both reverse payments and the patentee's odds of prevailing in infringement litigation are irrelevant. Watson Br. at 29-31, citing, *inter alia*, *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006), and *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010) ("*Cipro V*"), *pet. for cert. pending sub nom. Louisiana Wholesale Drug Co. v. Bayer AG*, No. 10-762 (filed Dec. 6, 2010). But this is a strawman, because, as explained above, regardless of what other courts have held, this Court has not held that reverse payments, or the patentee's odds of success in infringement litigation, are irrelevant. And although in *Cipro V* the Second Circuit affirmed the dismissal of the challenge, it did so because it was bound by the

[13] Defendants offer nothing to support their concern that, if the merits of the infringement action are relevant to the antitrust analysis of a settlement, then whenever infringement is disputed, the settlement will be deemed anticompetitive. *See* Watson Br. at 34. None of this Court's cases suggest such a *per se* approach, nor does the Commission do so here.

court's decision in *Tamoxifen*. 604 F.3d at 108. Indeed, the panel expressed particular concern that the result in *Tamoxifen* ran afoul of the purpose of Hatch-Waxman, and had given rise to numerous settlements involving reverse payments. *Id.* In any event, cases in other circuits are not uniform.[14] *See, e.g.*, *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 534 (E.D. Pa. 2010) (denying motion to dismiss antitrust challenge of patent settlement, and holding, *inter alia*, that allegations of patent invalidity and non-infringement are relevant to whether the patent's exclusionary scope has been exceeded, and that whether "side-term inducements" were legitimate business arrangements or constituted an antitrust violation, could only be assessed at trial).

[14] Defendants dismiss *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003), because they contend that it involved agreements that extended beyond the exclusionary potential of the patent at issue. *See* Watson Br. at 31 n.9. In that case, the court held that an agreement between a patent holder and a generic manufacturer, pursuant to which the generic manufacturer delayed marketing its generic version of Cardizem CD, was subject to *per se* condemnation under the antitrust laws. Although there were some aspects of the agreement that could possibly have extended beyond the scope of the patent that was at issue, the court's reasoning was not limited to those circumstances.

II. POLICY, SUPREME COURT PRECEDENT, AND CONGRESSIONAL INTENT ALL REQUIRE THIS PLAIN READING OF THIS COURT'S DECISIONS; IF CONSTRUED AS DEFENDANTS URGE, THE DECISIONS SHOULD BE RECONSIDERED EN BANC

Defendants argue that, to promote pharmaceutical innovation, the patent laws should trump the antitrust laws, and that this Court should create a virtually irrebuttable presumption in favor of settlement agreements with exclusion payments, regardless of their effect on competition. Watson Br. at 47-53. But the antitrust laws also seek to promote innovation (as well as competition). *In re Tamoxifen*, 466 F.3d at 201; *King Drug v. Cephalon*, 702 F. Supp. 2d at 524. Thus, there is a balance between the antitrust laws and the patent laws. *Valley Drug*, 344 F.3d at 1307-08. As the Supreme Court has made clear, even when patents are involved, agreements among potential rivals must still satisfy the antitrust laws. *See, e.g.*, *United States v. New Wrinkle Inc*., 342 U.S. 371, 378, 72 S. Ct. 350, 353 (1952); *United States v. Masonite Corp*., 316 U.S. 265, 277, 62 S. Ct. 1070, 1077 (1942).[15] This Court should reject defendants' attempt to create a presumption in favor of settlement agreements, regardless of their effect on

[15] Moreover, when Congress modified the Hatch-Waxman Act in 2003, it provided that agreements such as the ones entered into by defendants must, within 10 days after they are executed, be submitted to both the Commission and to the Antitrust Division of the Department of Justice. P.L.108-173§§ 1111-1118 (2003), codified at 21 U.S.C. § 355 note. This makes sure that both agencies have an opportunity to assess whether the agreements violate the antitrust laws.

competition.

Defendants' proposed rule would also upset the balance struck by Congress in the Hatch-Waxman Act. Hatch-Waxman seeks (1) to promote innovation by extending the term of pharmaceutical patents to compensate for the lengthy FDA approval process and (2) to increase the availability of low-cost generic drugs by streamlining the FDA-approval process for generics and by encouraging challenges to weak patents. *See* H.R. Rep. 98-857, Pt. I, at 14-15 (1984). Congress encouraged such challenges by rewarding the first generic entrant who challenges a patent with 180 days of marketing exclusivity. Thus, under Hatch-Waxman, innovators with strong patents are rewarded by an extended patent term, while companies with weak patents have those patents taken away through successful judicial challenges. Defendants argue that exclusion-payment agreements encourage challenges to patents. Watson Br. at 47-53. But their proposed rule flips the Congressional scheme on its head. To them, it would be acceptable for the holder of weak patent to pay its generic competitors to stay off the market until the patent has expired. Indeed, as the court recognized in *Tamoxifen*, such an agreement is most likely to occur when a patent is weak. 466 F.3d at 211. It makes no sense to permit such agreements that pay generics to stay out of the market when Congress created a bounty to encourage the opposite result. Indeed,

such payments encourage challenges against both strong and weak patents alike, because challengers would expect that the vast majority of challenges would simply result in exclusion-payment settlements.

Moreover, challenges filed in anticipation of such settlements do not engender the sorts of benefits that Hatch-Waxman seeks to promote: they do not result in any additional low-cost alternatives for consumers.[16] It makes no sense to permit agreements that pay generic marketers to stay out of the market when Congress has attempted to encourage the exact opposite result. And, as the Commission explained, such agreements delay generic entry beyond the date that would be justified by the strength of the patent.[17] FTC Br. at 50-52.

Defendants also contend that exclusion-payment agreements further the

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[16] Defendants claim that exclusion payment agreements allow the generic manufacturer to enter the market prior to the expiration of the patent. *See* Watson Br. at 47. But as this case shows, that benefit is often hollow. Although the agreements permit generic marketing of Androgel in 2015, five years prior to the expiration of Solvay's patent, Solvay is developing a product that will supplant Androgel, and it projects that it will be able to market this product by 2015. D.114 at ¶¶ 61-63. Thus, even though the agreements permit generic marketing five years before the nominal expiration of Solvay's patent, the complaint alleges that the agreements actually block generic marketing for the useful life of Solvay's patent.

[17] As the Commission explained in its opening brief, payment-free settlements allowing generic entry prior to a patent's expiration reflect the parties' true evaluation of the strength of a patent. Such settlements were particularly frequent between 2000 and 2005. However, that trend has reversed. *See* FTC Br. at 51 & n.37; *see also Cipro V*, 604 F.3d at 109 (suggesting a link between the increase in exclusion-payment settlements and its decision in *Tamoxifen*.

second goal of the Hatch-Waxman Act -- *i.e.*, the promotion of innovation -- by providing an additional reward to patent holders. Watson Br. 51. This argument, however, ignores the essential nature of Hatch-Waxman, which is a complex and finely-balanced enactment that seeks to adjust the benefits to both patent holders and generic challengers, for the ultimate benefit of the consuming public. *See* H.R. Rep. 98-857, Pt. 1, at 14-15. Provisions of Hatch-Waxman that lengthen the time period in which patents on drugs remain valid to compensate patent holders for time spent testing and seeking FDA approval are more directly geared to advancing its goal of promoting innovation. *See Id.* Even assuming that the availability of lucrative reverse-payment settlements may provide an added incentive to obtain new patents, it does so at the expense of consumers, by ensuring that even the most vulnerable patent claims will not be *effectively* challenged, but will result only in the sharing of monopoly rents by patent holders and nominal challengers. This is contrary to the balance that Congress has struck in the Hatch-Waxman Act, and it contravenes basic principles of antitrust law.

Accordingly, defendants' interpretation of this Court's precedents should be rejected. But if this Court interprets its previous decisions as defendants propose, this Court should reconsider those decisions, and should conclude that agreements such as the ones at issue here are presumptively unlawful. Outside the patent

context, payments made to keep potential competitors out of the market are per se antitrust violations. And the Hatch-Waxman Act shows that Congress did not intend to immunize such agreements when they involve pharmaceutical patents. Because agreements such as the ones at issue in this case are akin to agreements that are per se unlawful, they should be treated as presumptively unlawful. *See* FTC Opening Brief at 50-56.

III. THERE IS NO MERIT TO EITHER OF THE ARGUMENTS RAISED IN THE SEPARATE BRIEF OF PAR/PADDOCK

In their separate brief, Par and Paddock ("Par/Paddock") argue that their agreement with Solvay (unlike Watson's) is immune from antitrust scrutiny pursuant to the *Noerr* doctrine, which provides that "no violation of the [antitrust laws] can be predicated upon mere attempts to influence the passage or enforcement of laws." *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 135, 81 S. Ct. 523, 529 (1961). But the fundamental premise of their *Noerr* argument (that any restraint on competition derives from the consent judgment they requested) is wrong. Brief of Defendants-Appellees Par Pharmaceutical Companies, Inc., and Paddock Laboratories, Inc. ("Par/Paddock Br.") at 15-31.

First, the district court never approved (or even saw) the private agreements that the complaint alleges were essential to the parties' agreement to defer generic

marketing until 2015. D.114 at ¶ 80 ("[t]he parties did not file their settlement co-promotion, and back-up manufacturing agreements with the court"). Because the court was not apprised, prior to entry of the consent, of the terms of the parties' agreements, the resulting restraint cannot be attributed to the court's action. *See In re Ciprofloxacin*, 261 F. Supp. 2d 188, 212-13 (E.D.N.Y. 2003) (rejecting an argument similar to the one raised by Par/Paddock).

There is a second flaw with the *Noerr* argument. Even before the parties sought entry of the consent judgment, they had already entered into the binding anticompetitive agreement challenged by the Commission. D.114 at ¶ 80 (settlement, co-promotion, and back-up agreements not contingent on court approval).[18] And their stipulated injunction maintains their control over the date that Par/Paddock can market generic Androgel.[19] Thus, the anticompetitive harm is not "caused by the decision of a court," Par/Paddock Br. at 21(quoting *Andrx v. Biovail*, 256 F.3d 799, 818 (D.C. Cir. 2001)), and they cannot plausibly claim that

[18] *Noerr* does not provide immunity to an anticompetitive agreement that parties have already entered into merely because they ask the government to adopt or enforce it. *See, e.g., Columbia Steel Casting Co., Inc. v. Portland Gen. Elec. Co.*, 111 F.3d 1427, 1446 (9th Cir. 1997) ("PGE is not being held liable for filing the application * * * PGE is being held liable for agreeing with PP&L to replace competition with area monopolies").

[19] *See* Appendix to Par/Paddock Br., Tab E, ¶ 10 (injunction applies "[e]xcept as agreed to by the parties pursuant to the Agreements in settlement of this Litigation or otherwise"; ¶ 6 (parties may agree to permit Par/Paddock to enter before 2015).

they are merely "abiding by the court's order."[20] *Id*. at 20.

Par/Paddock also argue that their settlement does not violate the law because it caused no harm to competition. In particular, they assert that, under the Hatch-Waxman Act, they could not have entered the market earlier than Watson because Watson filed its application with the FDA prior to Paddock. Thus, they contend, there is no harm because their settlement permits them to enter at the same time as Watson. *See* Par/Paddock Br. at 32-43. This argument fails because it challenges the allegations in the Commission's complaint. The court below granted the defendants' Rule 12(b)(6) motion, and, as a result, the allegations of the complaint must be accepted as true. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949-53 (2009). Moreover, when resolving a 12(b)(6) motion, the only question for the court is whether the plaintiff's claims are "plausible," that is "above the speculative level"; the court must assume that the plaintiff can prove their truth "even if [the allegations are] doubtful in fact * * *." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555-56, 127 S. Ct. 1955, 1965 (2007).

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[20] *MedImmune, Inc. v. Genentech, Inc.*, 2003 WL 25550611 (C.D. Cal. Dec. 23, 2003), *see* Par/Paddock Br. at 21-27, does not advance Par/Paddock's cause. The dispute in *MedImmune* involved the priority of two patents. *Noerr* immunized the settlement because the court's order "overturn[ed] the [PTO]'s priority decision, [and this] could not have been accomplished through private agreement." Although Par/Paddock's settlement can be enforced through contempt, the elements of the underlying agreement were accomplished through private agreement.

The Commission's complaint alleges, in detail, that, but for their settlement with Solvay, Par/Paddock would have entered the market before 2015. The complaint also explains that, pursuant to Hatch-Waxman, even after Watson settled with Solvay, Par/Paddock could have gained FDA approval to market generic Androgel by successfully prevailing in the infringement litigation. These allegations, detailing how the settlement resulted in this delay, amply allege harm to competition.

Par/Paddock contend that, once Watson had entered into its settlement with Solvay, it became "implausible" that there was any circumstance under which they would have entered the market prior to 2015 (which was also the entry date agreed to by Watson). Par/Paddock Br. at 39. But the complaint contains allegations explaining why Par/Paddock would have done so. In particular, the complaint alleges that Par/Paddock would have prevailed in the infringement litigation, ¶ 94, and that Par had prepared forecasts showing that, even if it entered the market 180 days after Watson commenced marketing its generic version of Androgel, Par/Paddock would earn significantly more in profits than the litigation with Solvay would cost, ¶ 95. Indeed, Par/Paddock always knew that Watson would be able to enter before they did, regardless of whether any party ever entered into a settlement. Nonetheless, they sought FDA approval, and engaged in several years

of litigation so that they could obtain the right to follow Watson into the market. Nor is it implausible that Par/Paddock would have continued to litigate even after Watson entered into a settlement. Otherwise, Solvay would not have agreed to pay Par/Paddock $72 million in return for their agreement to refrain from marketing generic Androgel until 2015. Plainly, Solvay agreed to such a settlement because there was a substantial chance that Par/Paddock would have continued to litigate. Finally, it is plausible that, as the complaint alleges, absent payments, Solvay and Par/Paddock would have entered into an agreement providing for entry prior to 2015. ¶¶ 57, 70, 94. Thus, the allegations of the Commission's complaint are more than sufficient to survive a 12(b)(6) challenge.

CONCLUSION

For the reasons set forth above, and in the Commission's opening brief, this Court should reverse the district court's order dismissing the Commission's complaint, and remand this matter to that court for further proceedings.

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Certificate of Compliance

I certify that this brief complies with the type-volume limitation set forth in Fed. R. App. P. 32(a)(7)(B)(ii). It is proportionally spaced and contains 6935 words, as counted by the WordPerfect word processing program.

December 15, 2010

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Certificate of Service

I hereby certify that on December 15, 2010, I electronically filed the foregoing Reply Brief for Plaintiff-Appellant Federal Trade Commission at the Eleventh Circuit Court of Appeal's EDF website. Also on this day, I sent an original plus six paper copies of the Brief and Record Excerpts, via overnight delivery, to the Court, and I sent a paper copy (also by overnight delivery) to each of the following:

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