IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

Federal Trade Commission, *et. al.*, Plaintiffs, v. **Watson Pharmaceuticals, Inc.**, *et al.*, Defendants.	Civil Action File No. 1:09-CV-00955-TWT

Plaintiff Federal Trade Commission's Consolidated Opposition to Defendants' Motions to Dismiss

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INTRODUCTION

This case challenges collusive agreements to delay generic drug competition and share the resulting monopoly profits. By early 2006, Solvay faced competitive threats from Watson and Par, two companies seeking to market generic versions of AndroGel, Solvay's testosterone replacement drug. If generic entry were to occur, consumers would save hundreds of millions of dollars by purchasing low-cost generic alternatives. Solvay's sales, however, would plummet. To protect the revenues from its leading product, Solvay decided to purchase protection from competition, rather than try to convince this Court to bar generic entry based on the strength of Solvay's patent. Watson and Par agreed to accept a share of Solvay's monopoly profits – in exchange for abandoning their patent challenges and refraining from competing for nine years – because each realized it would profit more by colluding than competing.

The resulting restraint on generic competition thus flows not from the protection afforded by Solvay's patent, but rather from the "preference of the competitors for a mutual arrangement," one that "promises more profit if the parties abandon rather than maintain competition." *United States v. Masonite Corp.*, 316 U.S. 265, 281 (1942). The FTC's complaint alleges facts – including the terms of Solvay's agreements with its rivals, the circumstances under which these agreements were made, and the likelihood that the patent itself would not prevent generic entry –

that, if proven, would establish that the parties' contracts here exceeded the exclusionary potential of Solvay's patent.

According to defendants, none of these facts matter. Citing the Eleventh Circuit's decisions in *Andrx Pharmaceuticals., Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005), *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), and *Valley Drug Co. v. Geneva Pharmaceuticals., Inc.*, 344 F.3d 1294 (11th Cir. 2003), defendants contend that the mere possession of a patent conveys the inexorable right to exclude any challenger until the end of the patent term – a right that may be exercised by splitting monopoly profits with potential entrants to induce them to abandon their patent challenges and refrain from competing. The patent holder's right to purchase protection from competition, defendants argue, is not tempered by the strength of its patent, so long as the infringement claim is not a sham. (Defs.' Joint Mot. to Dismiss at 13.) Indeed, under defendants' end-of-patent-term standard, courts must disregard complaint allegations that the patent was invalid or so narrow that it would not prevent generic entry on its own.

The primary issue presented by defendants' motions is whether Eleventh Circuit precedent requires this Court to apply this end-of-patent-term standard to the arrangements challenged here. To be sure, the Commission has expressed its concern to the Supreme Court and Congress that the Eleventh Circuit adopted such a standard.

Others, however, including the Solicitor General, have interpreted the cases differently, noting that they did not expressly foreclose an inquiry into the strength of the patent in assessing an exclusion payment settlement. *See, e.g., Schering*, 402 F.3d at 1076. Indeed, while the Eleventh Circuit has stated that the antitrust analysis of a patent settlement must determine the extent to which the challenged agreement exceeds "the scope of the exclusionary potential of the patent" (*id*. at 1066), it also stressed "the need to evaluate the strength of the patent" (*id*. at 1076), an inquiry the end-of-patent-term standard expressly forecloses. Under the Solicitor General's reading of Eleventh Circuit precedent, the FTC's complaint states a claim.

This Court should apply that reading here to avoid conflict with Supreme Court precedent balancing patent rights with antitrust law. As discussed below, the end-of-patent-term standard misconstrues the nature of patent rights and inappropriately diminishes fundamental antitrust principles. Patent holders are most likely to use exclusion payments to protect the weakest patents – those that are least likely to be valid or infringed. Thus, under defendants' standard, even a trivial patent would give the patent holder the right to use its monopoly profits to buy protection from competition until patent expiration. Indeed, based on the threat to competition that inheres in patent settlements accompanied by a payment from the branded drug patent holder to a would-be generic rival, the Department of Justice considers such

settlements to be "presumptively unlawful," that is, illegal absent adequate justification.[1] The FTC has advocated a similar approach. The end-of-patent-term standard, by contrast, improperly views a branded drug company's purchase of protection from generic competition to be conclusively *lawful* (absent sham). By effectively barring consideration of whether such an agreement might violate the antitrust laws, this standard is inconsistent with the public interest in avoiding unwarranted patent monopolies.

Par's and Paddock's other arguments for dismissal should also be rejected. Their claim that the complaint fails to allege a cognizable anticompetitive effect misunderstands the Supreme Court's decision in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and ignores the FTC's well-pleaded factual allegations. Similarly, their claim of *Noerr* immunity is without merit because the harm from their agreement with Solvay is caused by private, not governmental, action.

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[1] Brief for the United States in Response to the Court's Invitation, at 21, *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, No. 05-2851 (2d Cir.), filed July 6, 2009, *available at* <http://www.usdoj.gov/atr/cases/f247700/247708.pdf> ("DOJ *Cipro* Amicus Br.").

BACKGROUND

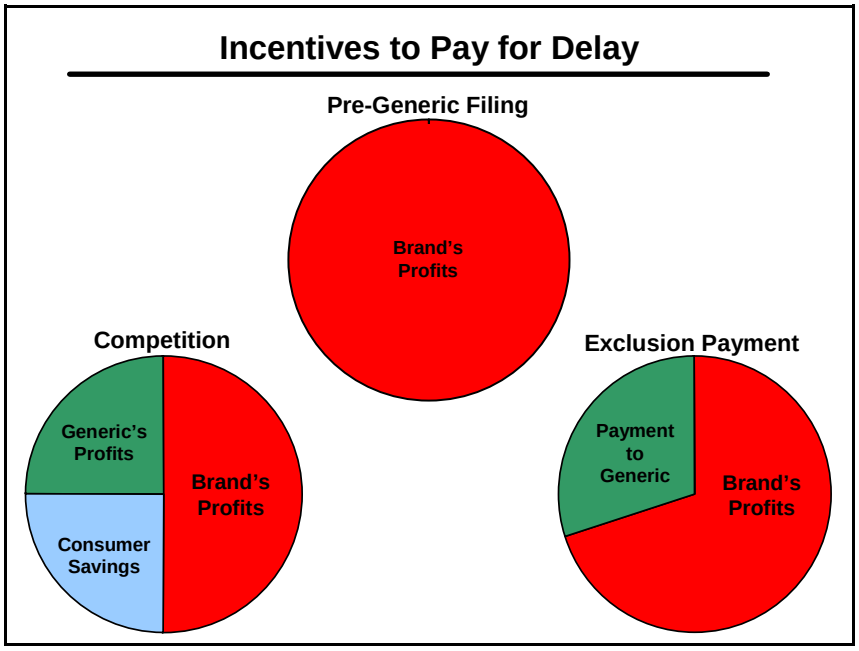
Competition under the Hatch-Waxman Act

Congress passed the Hatch-Waxman Act to make available more low-cost generic drugs, while fully protecting legitimate patent claims. The Act allows for accelerated FDA approval of a generic drug upon a showing, among other things, that the generic drug is "bioequivalent" to an existing branded drug. 21 U.S.C. § 355(j)(2)(A). It also establishes certain rights and procedures that apply when a company seeks approval to market a generic product before expiration of a patent relating to the counterpart branded drug. 21 U.S.C. § 355(j)(2). This framework encourages generic firms to challenge weak patents that would otherwise create unwarranted barriers to competition. *See, e.g.*, 21 U.S.C. § 355(j)(5)(B)(iv).

The Act has been remarkably successful. Generic challengers prevail in a majority of litigated cases. (SAC ¶¶ 29-30.) Generic competitors enter at steep discounts to branded drugs, and consequently, branded drugs' sales decline dramatically. (¶ 27.) As a result of the availability of lower-priced generics, American consumers have saved billions of dollars in prescription drug costs.

Although patent challenges have the potential for substantial consumer savings, the competitive dynamic between branded drugs and their generic equivalents creates an incentive for brand and generic firms to conspire to avoid competition and share

the resulting monopoly profits. The profits the generic expects to make will almost always be much less than the profits the brand stands to lose. Thus, it will be more profitable for both if the brand firm pays the generic to settle the patent dispute and agree to defer entry. (¶¶ 57-59.) Consumers, however, lose the possibility of earlier generic entry and the substantial savings that would result from price competition.



In recognition of the threat that such agreements pose, Congress amended the Hatch-Waxman Act in 2003 to require brand and generic companies to file patent settlement agreements with the FTC.[2] As a Senate report explained, those

[2] Pub. L. No. 108-173, Title XI, Subtitle B, 117 Stat. 2066, 2461 (contained in 21 U.S.C. § 355, historical notes).

amendments sought to stamp out the "abuse" of Hatch-Waxman law resulting from "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower cost drugs off the market."[3]

The Complaint Allegations

AndroGel and the threat of generic competition: Solvay sells a prescription gel containing synthetic testosterone that it markets under the name AndroGel. (SAC ¶ 31.) AndroGel has consistently been one of Solvay's highest selling products, with over $400 million in U.S. sales in 2007. (¶¶ 34, 36.) The only unexpired patent relating to AndroGel covers a formulation containing specified amounts of testosterone and certain other ingredients; it expires in 2020. (¶¶ 39, 43.) Patents covering synthesized testosterone expired decades ago. (¶¶ 31, 38.) Pharmaceutical gel products have also been available for decades. (¶ 32.)

In May 2003, Watson and Paddock (which later partnered with Par) each filed an application with the FDA for approval to market a generic version of AndroGel. (¶¶ 44, 46.) Each company certified to the FDA and to Solvay that its version of generic AndroGel did not infringe Solvay's patent, and that the patent was invalid or

[3] S. Rep. No. 107-167, at 4 (2002), *available at* <http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_reports&docid=f:sr167.pdf>.

unenforceable. (¶ 44.) In August 2003, Solvay filed patent infringement lawsuits against Watson and Paddock in this Court. (¶ 47.)

In January 2006, Watson received final FDA approval for its generic AndroGel product, which meant that Watson could lawfully launch its generic unless Solvay obtained a preliminary injunction. (¶ 52.) At that time, Solvay's CEO advised his superiors that Watson might launch generic AndroGel "at-risk" sometime in 2006. (¶ 53.) Solvay's fear was well-founded, as both Watson and Par were taking steps to prepare for a generic AndroGel launch. (¶ 54.) In fact, Par's CEO told investment analysts in early 2006 that if Par's generic AndroGel did not launch in 2006, it "should certainly hit in 2007." (¶ 55.) Solvay knew that when generic entry occurred, its branded AndroGel sales would plummet. (¶ 49.)

Defendants agree not to compete: Facing a threat of near-term generic competition, Solvay decided it wanted to defer generic entry for at least nine years, until 2015. (¶ 57.) But rather than seek a preliminary injunction from this Court to bar such entry based on the strength of its patent, Solvay sought to purchase exclusion from Watson and Par/Paddock with a share of its monopoly profits. (¶¶ 56, 67, 79.) Solvay knew from an internal financial analysis that Watson and Par/Paddock would not agree to a settlement that deferred generic entry until 2015 absent compensation. (¶¶ 57-59, 67, 79, Ex. A to SAC.) Solvay was right. During negotiations, Watson and

Par/Paddock both insisted on being paid a substantial amount to accept a 2015 entry date. (¶¶ 61-63, 70-74.) Solvay could afford to accept the generics' terms because by avoiding competition it would gain years of additional monopoly profits. (¶ 58.)

On September 13, 2006, Watson and Par/Paddock entered into separate settlements with Solvay, under which each generic agreed to abandon its patent challenge and forgo competing with its low-cost generic version of AndroGel until 2015. (¶¶ 65, 76.) These patent settlements took effect immediately; they were not contingent on court approval. (¶¶ 68, 80.) On the same day, Watson and Par/Paddock also entered into lucrative co-promotion and back-up manufacturing deals with Solvay under which they would share in the monopoly profits preserved by the generics' agreement to defer entry. The generic firms expect to be paid hundreds of millions of dollars over the life of these multi-year deals. (¶¶ 6, 66, 75, 77.)

On September 14, 2006, this Court entered a stipulation of dismissal in the Watson litigation and a consent judgment in the Par/Paddock litigation. (¶¶ 68, 80.) At the time of settlement, there had been no substantive rulings in the patent litigations. (¶¶ 86-90.) But given the substantial evidence the generics had developed (¶¶ 86, 88, 90), Solvay was not likely to meet its burden of proving that Watson and Par/Paddock infringed the formulation patent, nor was it likely to defeat the generics' arguments that the patent was invalid or unenforceable. (¶¶ 91-92.)

Effects of Defendants' Conduct: The challenged agreements deny consumers the potential benefits of competition from lower-priced generic versions of AndroGel until 2015, at a cost of hundreds of millions of dollars a year. (¶¶ 6, 94, 96, 98.) Moreover, absent the compensation that Solvay agreed to provide to Watson, Par, and Paddock, generic competition likely would have occurred prior to 2015, because one or both of the generics would have: (1) sold generic AndroGel "at risk" before the patent litigation was resolved; (2) prevailed in the patent litigation and sold generic AndroGel before 2015; or (3) agreed on settlement terms that did not involve compensation, but provided for generic entry earlier than 2015. (¶ 97.) In any event, even when Watson and Par can finally enter in 2015 under the agreements, consumers may realize few benefits from generic AndroGel because of Solvay's plans to switch sales from AndroGel to a different version of the branded drug before then. (¶ 99.)

Course of Proceedings

The FTC filed its complaint in the U.S. District Court for the Central District of California. On April 8, 2009, the California district court granted defendants' motion to transfer the case to this Court. The primary ground for the transfer was the court's belief that at least some of the FTC's claims would require a court to determine the likely outcome of the underlying patent suits.

ARGUMENT

In reviewing a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure, a district court must accept the allegations in a plaintiff's complaint as true and construe them in the light most favorable to the plaintiff. *Mancha v. Immigration & Customs Enforcement*, No. 06-2650, 2009 WL 900800, at *1 (N.D. Ga. Mar. 31, 2009) (Thrash, J.). Moreover, "the pleadings are to be construed broadly." *Watts v. Fla. Int'l Univ.*, 495 F.3d 1289, 1295 (11th Cir. 2007). At this stage, the appropriate question is "not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 563 n.8 (2007) (internal quotation marks omitted).

I. The Complaint States Valid Antitrust Claims Under Eleventh Circuit Precedent When That Precedent Is Construed Consistent with Supreme Court Authority

This antitrust case charges that an incumbent firm agreed to share its monopoly profits with its only two potential competitors to insulate its flagship product from competition until 2015. Paying a potential competitor to stay out of the market is a classic restraint of trade, and is presumptively anticompetitive, because it directly restricts competition on price and output. *See Palmer v. BRG of Ga.*, 498 U.S. 46, 49-

50 (1990) (per curium).[4] "[T]he law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." XII Herbert Hovenkamp, Antitrust Law ¶ 2030b at 213 (2005).[5] Citing these authorities, the Department of Justice correctly observed that it should be "presumptively unlawful" for a branded drug company to purchase delayed entry from uncertain generic competition: "Absent another explanation for it, such a payment is naturally viewed as consideration for the generic's agreement to delay entry beyond the point that would otherwise reflect the parties' shared view of the likelihood that the patentee would ultimately prevail in the litigation."[6]

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[4] *See also NCAA v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 107-08 (1984) ("Restrictions on price and output are the paradigmatic examples of restraints of trade that the Sherman Act was intended to prohibit.")

[5] *See, e.g., United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (en banc) (exclusionary conduct is unlawful when it "is aimed at producers of nascent competitive technologies as well as when it is aimed at producers of established substitutes"); *Engine Specialties, Inc. v. Bombardier Ltd.*, 605 F.2d 1 (1st Cir. 1979) (holding illegal a non-compete agreement between manufacturer and potential entrant that agreed to be exclusive distributor for incumbent).

[6] DOJ *Cipro* Amicus Br., *supra* note 1, at 10, 22. *See also In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) ("[I]t is one thing to take advantage of a monopoly that arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competition by paying the only potential competitor . . . to stay out of the market"); *Andrx Pharms. Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (on a motion to dismiss, it was reasonable to infer that payments to an allegedly infringing generic rival were to obtain protection that the patent did not provide).

According to defendants, however, an owner of an untested patent is entitled to pay a potential competitor to stay out of the market for the entire life of the patent.[7] Under their view of Eleventh Circuit law, so long as the underlying infringement claim is not a sham, the Court is prohibited from considering the strength of the patent as well as the anticompetitive effects of a patent settlement that excludes entry into the market. As discussed below, that standard conflicts with Supreme Court authority balancing patent rights with antitrust law, and Eleventh Circuit precedent should not be so construed.

Instead, the Court should construe Eleventh Circuit precedent to permit an inquiry into whether the source of the exclusion flows from the patent or from the sharing of monopoly profits. As the leading antitrust treatise observes: "[Intellectual property] rights, like all property rights . . . do not include rights to violate the antitrust laws unless a more particularized warrant can be found in the IP statutes or sound policy analysis." Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law, ¶ 2046c (2007 Supp.). Under this standard, the FTC's complaint states valid antitrust claims, and defendants' motions should be denied.

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[7] *See* Defs.' JM at 13 (asserting that settlement does not violate antitrust laws unless "the settlement delays generic entry beyond the end of the patent life").

A. Eleventh Circuit precedent should not be read to require this Court to apply defendants' end-of-patent-term standard

As defendants have emphasized, the FTC has expressed its concern to the Supreme Court and Congress that the Eleventh Circuit has adopted an expansive view of the exclusionary scope of patents. But the Eleventh Circuit decisions are not without ambiguity. In *Valley Drug*, the Eleventh Circuit held that exclusion payments were not *per se* unlawful "merely because" of a subsequent determination of patent invalidity. *Valley Drug*, 344 F.3d at 1306, 1308. The Court, however, remanded the case for consideration of the "protection afforded by the patents" based on "the likelihood of [the patentee] obtaining such protections" at the time of the agreement. *Id.* at 1312. On remand, the district court assessed the merits of the patentee's claim and concluded that the patentee was not likely to have obtained a preliminary injunction blocking generic entry. *In re Terazosin Hydrocholoride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1319 (S.D. Fla. 2005). The district court held on summary judgment that the patentee exceeded the protection afforded by its patent and violated the antitrust laws by paying the generic to stay off the market. *Id.* at 1319.

In *Schering*, when the Eleventh Circuit stated that the antitrust analysis of a patent settlement must determine the extent to which the challenged agreement exceeds "the scope of the exclusionary potential of the patent" (402 F.3d at 1066) it

stressed the "need to evaluate the strength of the patent." *Id.* at 1076. And in *Andrx*, the Eleventh Circuit – which held that the district court improperly dismissed the plaintiff's antitrust claims on the pleadings – suggested that the scope of the patent's exclusionary potential should be assessed in light of whether the relevant patent is "necessary" to the manufacture and sale of a generic product. 421 F.3d at 1235.

Others have noted that the Eleventh Circuit (unlike some other appellate courts) has not expressly foreclosed an inquiry into the strength of the patent. For example, the Solicitor General observed that "[n]either *Valley Drug* nor [*Schering*] holds . . . that evidence of invalidity or non-infringement available at the time of the settlement would be irrelevant in assessing the permissibility of a reverse payment."[8] Fifty-four legal scholars and other academics describe the Eleventh Circuit as applying "its own modified version of the rule of reason that inquires into the underlying validity of the patent before characterizing the conduct."[9] And the respondents in the *Schering* case

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[8] Brief for the United States as Amicus Curiae at 17-18, *FTC v. Schering-Plough*, 548 U.S. 919 (2006) (No. 05-273), *available at* <http://www.usdoj.gov/atr/ cases/f216300/ 216358.pdf>.

[9] Brief Amici Curiae of 54 Intellectual Property Law, Antitrust Law, Economic and Business Professors, the American Antitrust Institute, the Public Patent Foundation, and the AARP in Support of the Petitioner at 4, *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, 129 S. Ct. 2828 (2009) (No. 08-1194) (cert. denied) ("Academic *Cipro* Amicus Br."). *See also Kaiser Found. Health Plan Inc. v. Abbott Labs., Inc.* 552 F.3d 1033, 1041 (9th Cir. 2009) (explaining that, in *Valley Drug*, the Eleventh Circuit indicated "that the district

told the Supreme Court that the Eleventh Circuit's decision permits an inquiry into the "the strength of Schering's patent case."[10] The FTC's complaint contains a variety of allegations about the strength of Solvay's patent, including that Solvay was unlikely to preclude generic entry by enforcing its patent. (SAC ¶¶ 86-92). To the extent this Court interprets Eleventh Circuit precedent to permit such an inquiry, the complaint amply alleges that Solvay's conduct exceeded the "exclusionary potential of [its] patent." *Schering*, 402 F.3d at 1066.

B. The end-of-patent-term standard is inconsistent with the Supreme Court's view of the nature of patent rights

It has long been clear that a patent is not an iron-clad right to exclude. When a patent holder seeks to enforce its patent against an alleged infringer, it has the burden of proving that the challenged product falls within the scope of a patent's claims as properly construed. *See Markman v. Westview Instr.*, 517 U.S. 370, 374 (1996) ("Victory in an infringement suit requires a finding that the patent claim 'covers the alleged infringer's product or process' . . . ."). A patent holder's infringement

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court might be able to find a per se violation [of Section 1 of the Sherman Act] if it reframed its analysis" of the exclusion payment settlement at issue in that case.)

[10] Brief in Opposition at 23, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273) (cert. denied) (stating that the Court of Appeals decision "accommodates" the goals of Hatch Waxman because it permits a judgment about the exclusionary potential of Schering's patent based on the evidence adduced at trial concerning the strength of Schering's patent case).

accusation creates no presumption that the challenged product actually infringes. And while patent holders enjoy a statutory presumption of validity, that presumption is rebuttable and simply places the burden of persuasion on the party challenging validity. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007). Alleged infringers frequently meet this burden, resulting in rulings that invalidate the patent.[11]

A patent holder seeking to exclude a rival prior to final adjudication of the patent dispute thus must obtain a preliminary injunction. The patentee cannot merely assert in good faith that the challenged product infringes, nor can it sit back and rely on the presumption of validity.[12] Instead, like other litigants, it must establish its right to relief by showing, among other things, a likelihood of success on the merits. *See, e.g., eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). Moreover, the Supreme Court's decision in *eBay* – which issued after the Eleventh Circuit decisions

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[11] *See, e.g., Daiichi Sankyo Co., Ltd. v. Apotex, Inc.*, 501 F.3d 1254 (Fed. Cir. 2007) (patent covering method of treating ear infections with ofloxacin held invalid)*; Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007) (patent covering high blood pressure drug Altace found invalid); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286 (Fed. Cir. 2006) (claims of patent infringement related to extended release urinary incontinence drug Ditropan XL held invalid and not infringed).

[12] *See, e.g., Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1335 (Fed. Cir. 2006) (vacating grant of preliminary injunction and stating "'if [the defendant] raises a substantial question concerning . . . validity, i.e., . . . [an] invalidity defense that the patentee cannot prove 'lacks substantial merit,' then the patentee has not established a likelihood of success on the merit") (citations omitted).

at issue here – made it clear that even successful patentees do not have an absolute "right to exclude" demonstrated infringers.[13] *Id.* at 392. Rather, patentees must establish entitlement to a permanent injunction under the analysis generally applicable to equitable relief. *Id*. By overturning the Federal Circuit's prior rule, the Supreme Court explicitly rejected the argument that a patentee's "right to exclude"[14] justifies injunctive relief for successful patent litigants in every case. *Id.* ("[T]he creation of a right is distinct from the provision of remedies for violations of that right.").

Treating a patentee's *unproven* "right to exclude" as an absolute entitlement to purchase a permanent injunction with monopoly profits is thus flatly inconsistent with these Supreme Court patent law principles. As these cases make clear, until a patentee obtains a court judgment, the patent's potential power to exclude competitors is tempered by the risk that the patentee's arguments will fail to convince the court. In pharmaceutical patent litigation, the risk that the patentee will fail in its attempt to exclude is substantial: the patentee loses in 70 percent of the cases, according to two

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[13] District courts hearing patent cases "may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283.

[14] 35 U.S.C. § 154(a)(1) grants patentees "the right to exclude others from making, using, offering for sale, or selling the invention."

studies.[15] To be sure, the patentee can avoid the risk of losing its patent dispute by settling prior to judgment and agreeing to a patent license.[16] In that context, the stronger the patentee's validity and infringement arguments, the more advantageous the terms it can negotiate.[17] When a patentee asserts its patent and threatens a lawsuit with the goal of excluding a competitor from the market, the strength of its patent may either convince the accused infringer to accede or convince a court to issue an injunction. In either case, the exclusion results from the strength of the patent.

According to the end-of-patent-term standard, however, a patentee with monopoly power need not rely on the strength of its patent to prevent competition.

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[15] An analysis of Federal Circuit pharmaceutical patent claim decisions from 2002 through 2004 in which the court made a final ruling on the merits found that alleged infringers succeeded in 70 percent of the cases. Paul Janicke & Lilan Ren, *Who Wins Patent Infringement Cases?* 34 AIPLA Q.J. 1, 24 (2006) (attached as Ex. 1). An FTC study of all patent litigation initiated between 1992 and 2000 between brand drug manufacturers and Paragraph IV generic applicants found that when cases were litigated to a decision, the generics prevailed in cases involving 73 percent of the challenged drug products. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, 19-20 (July 2002), *available at* <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

[16] In fact, pharmaceutical patent holder can, and do, settle litigation without exclusion payments. (*See* SAC ¶ 101.)

[17] *See, e.g.*, Michael J. Meurer, *The Settlement of Patent Litigation*, 20 RAND J. ECON. 77, 77-79 (1989) (a patentee will often settle a dispute by licensing the patent in exchange for royalty payments to avoid the threat of having its patent invalidated; the terms of the license depend, in part, on the probability of the patentee's prevailing in litigation) (attached at Ex. 2).

Instead, it can achieve what its patent alone does not, by sharing its monopoly profits with its rivals. By permitting patentees to buy off competition until patent expiration, the end-of-patent-term standard grants trivial patents – those that are likely invalid or of narrow scope and easy to design around – the same exclusionary force as strong patents. In fact, the incentive to pay a generic to abandon its patent challenge is likely to be greatest when the patent infringement claim is weak.

The end-of-patent-term standard thereby upsets the carefully crafted balance that Congress struck in the Patent Act.

> From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.

Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146 (1989). As the Supreme Court stated in *KSR*, were the patent system to protect trivial inventions with exclusive rights, "patents might stifle, rather than promote, the progress of useful arts." 550 U.S. at 427. Indeed, "[g]ranting patent protection to advances that would occur in the ordinary course without real innovation retards progress" by preventing the public from using ideas that would otherwise be freely available. *Id.* at 419.

The Supreme Court has made clear that patent law must be construed and applied "to give effect to the public policy which limits the granted monopoly strictly

to the terms of the statutory grant." *United States v. Univis Lens Co.*, 316 U.S. 241, 251 (1942). "It is the public interest which is dominant in the patent system." *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 665 (1944). For that reason, a long line of Supreme Court cases has held that a licensee may later attack the validity of the patent under which it was licensed.[18] In *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969), the Court explained that this result is necessary to vindicate "the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain." Otherwise, "the public may continually be required to pay tribute to would-be monopolists without need or justification." *Id*.[19] The end-of-patent-term standard – by allowing a patent holder to avoid scrutiny of a weak patent simply by agreeing to split monopoly profits with patent challengers – is flatly inconsistent with Supreme Court authority.

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[18] *See, e.g., MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (holding that a licensee need not stop paying royalties in order to seek a declaratory judgment that the underlying patent is invalid, unenforceable, or not infringed).

[19] *See also Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found*., 402 U.S. 313, 349-50 (1971) (noting the Court's "consistent view" that a patentee "should not be insulated from the assertion of defenses and thus allowed to exact royalties for the use of an idea that is not in fact patentable or that is beyond the scope of the patent monopoly granted").

C. The end-of-patent-term standard disrupts the Supreme Court's balance of patent rights with antitrust law

The end-of-patent-term interpretation of Eleventh Circuit precedent also conflicts with two lines of Supreme Court authority balancing patent rights with antitrust law. The Supreme Court has held that the use of a patent settlement to share monopoly profits with patent challengers to induce them to stay out of the market does not fall within the patent holder's exclusionary grant, and violates the antitrust laws. *See United States v. Masonite Corp.*, 316 U.S. 265, 279 (1942).[20] In *Masonite*, a patent owner sued or threatened to sue its potential competitors for patent infringement. To resolve these disputes, the patent owner licensed the competing firms to sell its product, but at a price that it set. In return, the alleged infringers abandoned their efforts to sell their own, competing product. Addressing these facts, the Supreme Court noted that a "patentee who employs such an agent to distribute his product certainly is not enlarging the scope of his patent privilege if it . . . operates

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[20] Agreements that allow competitors to share the benefits of not competing are anticompetitive whether they involve price fixing agreements (as in *Masonite*) or payments not to compete (as alleged here). *See Blue Cross & Blue Shield United of Wis. v. Marshfield Clinic*, 65 F.3d 1406, 1415 (7th Cir. 1995) ("It would be a strange interpretation of antitrust law that forbade competitors to agree on what price to charge, thus eliminating price competition among them, but allowed them to divide markets, thus eliminating all competition among them."); *Gen. Leaseways, Inc. v. Nat'l Truck Leasing Ass'n*, 744 F.2d 588, 594-95 (7th Cir. 1984) ("raising price, reducing output, and dividing markets have the same anticompetitive effects").

only to secure to him the reward for his invention which Congress has provided." *Id.* at 279. But the Court held that a patent holder does more than secure a reward for its invention when it shares monopoly profits with potential competitors to entice them to abandon their own products and patent challenges:

> Active and vigorous competition then tend[ed] to be impaired, not from any preference of the public for the patented product, but from the preference of the competitors for a mutual arrangement for price-fixing which promises more profit if the parties abandon rather than maintain competition.

Id. at 281. There is no suggestion in *Masonite* that the patent owner restrained competition "beyond the end of the patent life." (Defs.' JM at 13.) Nonetheless, the Supreme Court found that the licenses exceeded the patentee's legitimate patent rights, and constituted an illegal sharing of monopoly profits.[21]

This is the crux of the antitrust claim here. As in *Masonite*, the complaint alleges that Solvay sued its potential competitors for patent infringement, and then settled. As in *Masonite*, Solvay then used business arrangements that were entered into in connection with these settlements to align the interests of would-be competitors to promote sales of Solvay's product and share in the resulting monopoly profits. As

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[21] *See also United States v. New Wrinkle Inc.*, 342 U.S. 371 (1952) (holding price-fixing agreement involving an unresolved patent dispute unlawful under the antitrust laws, notwithstanding that the patent holder might have secured a court judgment excluding all competition to the end of the patent life).

in *Masonite*, by sharing profits with its potential rivals, Solvay induced them to forgo their patent challenges and stay off the market until a date nine years in the future, without regard to the exclusionary force – or lack thereof – of Solvay's patent. *See Masonite*, 316 U.S. at 281 (sharing monopoly profits is a "powerful inducement to abandon competition"). Thus, the restraint on generic competition flows not from the protection afforded by Solvay's patent but rather from the "preference of the competitors for a mutual arrangement," one that "promises more profit if the parties abandon rather than maintain competition." *Id*.

Applying the end-of-patent-term approach would also conflict with well-settled Supreme Court law that permits the government to contest the claimed scope and validity of the patent grant in an antitrust challenge. In *United States v. United States Gypsum Co.*, 333 U.S. 364 (1948), the Supreme Court made clear that the government may challenge the validity of a patent that an antitrust defendant (like defendants here) asserts to justify otherwise anticompetitive agreements. The Court rejected the lower court's contrary holding, stating that in an antitrust enforcement action to vindicate the public interest, the government should have the opportunity to "show that the asserted shield of patentability does not exist." *Id.* at 388.[22] In *United States v. Glaxo Group*

[22] The Court derived this principle from cases holding that "[i]n an antitrust suit instituted by a licensee against his licensor . . . the licensee may attack the validity of the patent under which he was licensed, because of the public interest in

Ltd., 410 U.S. 52 (1973), the Supreme Court reaffirmed this conclusion. As the Court explained, where the government questions a patent's validity in an antitrust challenge, "we perceive no good reason, either in terms of the patent system or of judicial administration, for refusing to hear and decide it." *Id.* at 111.

Thus, while an antitrust court should not need to assess direct evidence of the underlying patent claims to evaluate exclusion payments, a court certainly is not legally precluded from doing so.[23] Defendants conceded this point in their transfer motion, where they argued that the "Court that resolves the Government's antitrust allegations must weigh the patent merits." (Defs.' Joint Reply in Support of Mot. to Transfer Venue at 3.) In any event, the *Gypsum* and *Glaxo* principle that the government may challenge an assertion that an untested patent would bar antitrust liability is consistent with the long line of Supreme Court cases upholding the public

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free competition." *Id.* at 387 (citing *Sola Elec. Co. v. Jefferson Elec. Co.*, 317 U.S. 173 (1942) and *Edward Katzinger Co. v. Chi. Metallic Mfg. Co.*, 329 U.S. 394 (1947)).

[23] As noted above, a branded drug company's sharing of its monopoly profits to secure a settlement from its generic rivals should be presumptively unlawful. While a defendant might try to rebut that presumption of illegality with proof that the amount of exclusion is commensurate with the strength of its patent, as the Department of Justice correctly observed, "there is no need to determine whether the patent would in fact have been held invalid [or not infringed] to conclude that the settlement likely disadvantaged consumers." DOJ *Cipro* Amicus Br., *supra* note 1, at 26. Should this Court deem it appropriate, however, the FTC is prepared to offer direct evidence of the patent merits in this case.

interest in avoiding protection of unwarranted patent monopolies: "It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly." *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892).

D. The end-of-patent-term standard improperly gives private agreements the antitrust protection afforded government petitioning

Enforcement of a patent through litigation normally does not implicate the antitrust laws, even though such a suit by its nature seeks to eliminate competition. The Supreme Court has held that the Sherman Act does not prohibit petitioning the government for an anticompetitive result (*see E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961)), and that filing a lawsuit is petitioning. *See Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508 (1972). Consequently, absent a sham infringement claim or fraud, patent enforcement through litigation enjoys antitrust immunity. *See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993) (filing of non-sham lawsuit is protected from antitrust challenge); *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965) (fraud in procuring patent deprives patentee of immunity that normally protects bringing of an infringement action).

Of course, as discussed above, when patent holders choose this protected avenue of enforcement they face the risk that their patent may be found invalid, not infringed, or unenforceable. Alternatively, they can avoid this risk by settling their infringement claim. Settlements are generally encouraged, as they save private and court resources. But private agreements that settle litigation do not enjoy the antitrust immunity afforded to petitioning the government through litigation. *See, e.g., United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963) (cross-licensing agreement resolving patent litigation not entitled to antitrust immunity). The patentee, therefore, may choose between litigation to enforce the patent – with antitrust immunity but the risk that the suit will be unsuccessful – and non-petitioning action through settlement, which avoids the risk of an adverse decision but offers no antitrust immunity.[24]

The end-of-patent-term standard "treats a private settlement agreement excluding competition as the equivalent of a litigated judgment affirming the validity of the patent." DOJ *Cipro* Amicus Br. at 15. Applying the sham/fraud standard to such non-petitioning conduct enables patent holders to have it both ways: they can use collusive agreements to avoid the risk that patent litigation could lead to an

[24] The large majority of patent settlements, including those outside the Hatch-Waxman context, pass antitrust muster under an analysis that takes into account their procompetitive benefits. The point here is that patent settlements do not enjoy the broad antitrust immunity afforded to litigation.

unfavorable outcome, but still enjoy the protection from antitrust scrutiny afforded to enforcement though litigation. But as discussed above, the risk that a patent infringement claim will be unsuccessful is fundamental to the carefully-crafted balance that Congress struck in the Patent Act. *See Pope Mfg.*, 144 U.S. at 234. Defendants' reading of Eleventh Circuit precedent – as immunizing a settlement from antitrust scrutiny to the same degree as the filing of a lawsuit – is inconsistent with that balance.

E. Court decisions adopting the end-of-patent-term standard have been widely criticized on legal and policy grounds

To be sure, the end-of-patent-term standard has been adopted in other Circuit decisions, namely the majority opinion in *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006), and the opinion in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008). Each of these decisions accepts the fundamental premise that, absent an allegation of sham or fraud, the existence of a patent entitles the owner to purchase the equivalent of a permanent injunction until patent expiration.

These appellate decisions, however, have been widely criticized on legal and policy grounds. The Solicitor General, for example, in an amicus brief to the Supreme Court, called the standard set forth in *Tamoxifen* "erroneous" and an "insufficiently

stringent standard for scrutinizing patent settlements."[25] As the Solicitor General observed, "the interests in consumer welfare protected by the antitrust laws militate against adoption of a legal standard that would facilitate a patent holder's efforts to preserve a *weak* patent by dividing its monopoly profits with an alleged infringer." U.S. *Tamoxifen* Amicus Br. at 11 (emphasis in original). *See also Tamoxifen*, 466 F.3d at 228 (Pooler, J., dissenting) ("[T]he majority's requirement that an antitrust plaintiff show that a Hatch-Waxman lawsuit settled by agreement was a sham . . . is unjustified. A more searching inquiry and a less stringent standard are required to properly protect all interests.").

Fifty-four legal scholars, economics professors, and other academics criticized the Federal Circuit's *Cipro* opinion as "far outside the mainstream of judicial and academic analysis" and containing "fundamental errors of economic reasoning."[26] Representative Henry A. Waxman, an original sponsor of the Hatch-Waxman Act, stated that the appellate courts' permissive treatment of exclusion payment agreements has "turned the policies of the underlying federal legislation on their head."[27] The

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[25] Brief for the United States as Amicus Curiae, at 12-13, *Joblove v. Barr Labs. Inc.*, 127 S. Ct. 3001 (2007) (No. 06-830), *available at* <http://www.usdoj.gov/osg/briefs/2006/2pet/6invit/2006-0830.pet.ami.inv.pdf>.

[26] Academic *Cipro* Amicus Br., *supra* note 9, at 2, 4.

[27] Motion and Brief of Representative Henry A. Waxman as *Amicus Curiae*

American Medical Association and consumer groups, such as AARP and Consumers Union, have expressed concerns that exclusion payment settlements "create barriers to affordable prescription drugs and impose substantial costs on the health care system as a whole," and that courts have blessed "patently anticompetitive settlements."[28]

In fact, the Second Circuit is revisiting the rule adopted in *Tamoxifen*. That court currently is hearing an appeal of antitrust cases involving the same exclusion payment settlement that was upheld by the Federal Circuit in *Cipro*. Notwithstanding its own *Tamoxifen* precedent, the Second Circuit invited the Department of Justice to address the legality of a brand paying its potential generic rival to abandon its patent challenge and refrain from competing. In response, the Department of Justice reiterated its criticism of the *Tamoxifen* standard, stating that "[t]he anticompetitive potential of reverse payments in the Hatch-Waxman context in exchange for the alleged infringer's agreement not to compete . . . is sufficiently clear that such

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in Support of Petitioner at 1, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), *available at* <http://www.citizen.org/documents/waxmanamicus.pdf>.

[28] *See* Statement of the American Medical Association to the Subcommittee on Commerce, Trade, and Consumer Protection, Committee on Energy and Commerce, *Impact of "Pay-for-Delay" Settlements On Patient Access to Affordable Generics and Overall Health Care System Costs*," at 1 (Apr. 13, 2009) (attached as Ex. 3). Letter to Eric H. Holder, Jr., Attorney General, from AARP, et al. (April 17, 2009) at 4 (attached as Ex. 4).

agreements should be treated as presumptively unlawful under Section 1 of the Sherman Act."[29] The cases remain pending before the Second Circuit.

II. The Complaint Amply Alleges that Solvay's Payments to Par/Paddock to Defer Generic Entry until 2015 Harm Competition

The complaint amply alleges that the exclusion payment settlement among Solvay, Par and Paddock harms competition, by providing more protection from competition than Solvay's patent provides. A number of well-pleaded factual allegations support this conclusion. *See infra* at 32-35. Par and Paddock (but not Solvay) argue, however, that some of these allegations are implausible, and must be ignored under *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007). (Par's Mot. to Dismiss at 21-25.) This argument is without merit.

Even after *Twombly*, a district court weighing a motion to dismiss "must accept the facts pleaded in the complaint as true and construe them in the light most favorable to the plaintiff." *Mancha*, 2009 WL 900800, at *1. While *Twombly* requires a plaintiff to plead enough facts to "'raise a right to relief above the speculative level,'" it does not permit a court to ignore well-pleaded factual

[29] DOJ *Cipro* Amicus Br., *supra* note 1, at 10. *See also id.* at 15 ("The Tamoxifen standard . . . upsets the carefully crafted balance that Congress struck in the Patent Act.").

allegations "simply because 'it strikes a savvy judge that actual proof of those facts is improbable.'" *Watts*, 495 F.3d at 1295 (quoting *Twombly*, 550 U.S. at 556).

Par's and Paddock's argument rests on the assertion that their exclusion payment settlement cannot possibly harm competition because it provides for entry by Par/Paddock (the second generic filer) at the same time in 2015 as Watson (the first filer). (Par's Mot. at 16-25.) But the complaint sets forth well-pleaded factual allegations explaining why Par would have entered before 2015 – regardless of whether Watson settled – had it not received a share of Solvay's monopoly profits. (SAC ¶¶ 54-55, 79, 94-97.)

First, the FTC alleges that, but for its exclusion payment settlement, Par would have marketed generic AndroGel before a final decision in the patent litigation. (SAC ¶ 97.) This is not only plausible, it is precisely what Par itself expected before settling with Solvay. Par's CEO told investors in early 2006 that Par expected to market generic AndroGel in 2006 or 2007, well before any appeal in the patent litigation would have been completed. (SAC ¶ 54.) As the complaint alleges, Par expected that Watson would launch its generic product "at risk" in the near term, and that Par would then follow "at risk" six months later, when Watson's exclusivity expired. (*Id.*) As it turned out, Watson relinquished its 180-day Hatch-Waxman

exclusivity rights when it settled with Solvay. (Par's Mot. at 21.) Thus, Par would have been free to launch generic AndroGel "at risk" at any time thereafter.

Second, the FTC plausibly alleges that, absent a settlement, Par would have prevailed in the patent litigation and marketed generic AndroGel well before 2015. (SAC ¶ 94.) According to the complaint, absent receiving significant compensation, neither Par nor Watson would have agreed to defer entry until 2015. If the litigation continued, the complaint alleges that both generics would have prevailed and entered well before 2015. (SAC ¶¶ 67, 79, 96-97.) Even if Solvay had settled with Watson but not Par on a 2015 entry date, the complaint alleges that Par had ample financial incentives to continue challenging Solvay's patent. Par complains this allegation is "diseconomic" (Par's Mot. at 23), but its own internal forecasts clearly support it. (SAC ¶ 95.) In fact, it is not unusual in Hatch-Waxman patent litigation for later filers to continue to litigate even after the first filer has settled.[30] Whether Par would have

[30] *See, e.g., Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293 (Fed. Cir. 2007) (reversing district court ruling against second filer Lupin and holding pharmaceutical patent invalid – 18 months after branded patent holder had settled with generic first filer Cobalt Pharmaceuticals, *see* <http://www.fda.gov/ohrms/dockets/dockets/07n0382/07n-0382-let6.pdf>).

continued to litigate in this circumstance is an issue to be resolved at trial, not on a motion to dismiss – where the FTC's allegations must be accepted as true.[31]

Third, the FTC plausibly alleges that, absent compensation, Solvay and Par would have entered a settlement providing for generic entry before 2015. (SAC ¶ 97.) The complaint alleges that Solvay could not secure a 2015 entry date without paying the generics – as Solvay's own financial analysis showed. (*Id.* ¶¶ 57, 61, 67, 70, 79, 96, Ex. A to SAC). If either Par or Watson (or both) had balked and instead insisted on an earlier (payment-free) entry date, Solvay may have agreed to an earlier date with either or both. Par may dispute this proposition at trial, but it may not do so on a motion to dismiss.[32]

The FTC's complaint contains ample and detailed factual allegations that if proven would establish the anticompetitive nature of Par's settlement with Solvay.

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[31] *See William O. Gilley Enters. v. Atl. Richfield Co.*, 561 F.3d 1004, 1011 (9th Cir. 2009) (citing *Twombly*, rejecting argument that antitrust plaintiffs failed to allege anticompetitive effects, and stating "[a]t the stage of a motion to dismiss for failure to state a claim, it is not our role to determine the soundness of Plaintiffs' economic theory").

[32] Par relies on *Schering* to support its argument that an alternative settlement theory is "untenable," but the Eleventh Circuit's conclusion in that case was based on a full record from an administrative trial. (Par Mot. at 24-25(citing *Schering*, 402 F.3d at 1066 n.15).) Here, the FTC should have the opportunity to present evidence regarding Solvay's pre-settlement financial analysis, which showed that an earlier entry date was indeed expected with a no-payment settlement. (SAC ¶ 57 and Ex. A. to SAC)

Par directly contradicts these allegations in its motion papers, and suggests that proof is required at the pleading stage. Even after *Twombly*, that is not so. *See, e.g.*, *United Tech. Corp. v. Mazer*, 556 F.3d 1260, 1272-73 (11th Cir. 2009) (citing *Twombly*, denying motion to dismiss, and noting that "the jury will have a chance to resolve this question of fact"); *Watts*, 495 F.3d at 1298 ("We are at the pleading stage, not the proof stage."). The Federal Rules of Civil Procedure do not require more than the allegations contained in the FTC's detailed 44-page complaint.

III. The Consent Judgment Does Not Confer *Noerr* Protection on Par/Paddock's Agreement with Solvay

The essence of the *Noerr* doctrine, first articulated in *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, is that parties do not violate the antitrust laws when they merely seek anticompetitive action from the government. 365 U.S. 127, 135 (1961) ("[N]o violation of the [Sherman] Act can be predicated upon mere attempts to influence the passage or enforcement of laws").[33] *Noerr* thus distinguishes between agreements to advocate and agreements on marketplace behavior. *See, e.g., FTC v. Superior Court Trial Lawyers Ass'n*, 493 U.S. 411, 424-26

[33] *Noerr* addressed joint advocacy to influence a legislature. Subsequent decisions extended the doctrine to petitioning before executive agencies (*e.g., United Mine Workers v. Pennington*, 381 U.S. 657 (1965)), and courts (*e.g., California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972)).

(1990) (distinguishing protected lobbying campaign from attorneys' unprotected illegal boycott to induce government to enact legislation).

The *Noerr* doctrine does not apply to the conduct challenged here. The FTC's complaint challenges private agreements that directly restrain trade – not any request by defendants that the government (including this Court) restrain trade for them. Indeed, Par and Paddock do not contend that their agreement to refrain from competing with Solvay for nine years constitutes petitioning or conduct merely incidental to petitioning.[34] Instead, they try to concoct a *Noerr* defense out of this Court's entry of a consent judgment in the patent case. Their *Noerr* argument, however, rests on the erroneous premise that the restraint on Par's entry results from the consent judgment. It plainly does not.

The defendants' anticompetitive agreement created the restraint without regard to any action by this Court. The subsequent entry of the consent judgment did not transform the cause of the harm from their private agreement into government action. Under the terms of their requested consent order, defendants continue to maintain control over the timing of Par/Paddock's entry. Moreover, defendants failed to

[34] *Noerr* immunized a publicity campaign aimed at the general public because it was incidental to the effort to secure favorable legislation. 365 U.S. at 143. Courts have rejected the argument that settlements are merely incidental to the litigation process and therefore automatically entitled to *Noerr* protection. *See, e.g., Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001).

disclose to the Court material terms of their agreement. For each of these reasons, Par/Paddock's claim that this Court's action is responsible for the consumer harm from their agreement with Solvay is untenable. Thus, even if their request for entry of a consent judgment could be properly deemed "petitioning" for *Noerr* purposes, their causation argument for *Noerr* immunity fails.

A. The challenged restraint is private, not governmental, action

Acting in concert with Solvay, Par/Paddock created the challenged restraint without any aid from this Court. Like Watson, Par/Paddock agreed with Solvay to refrain from marketing a generic AndroGel product for nine years, in exchange for a share of Solvay's profits preserved by avoiding generic competition. (SAC ¶¶ 5-6, 64-67, 69-79.) In each case, the restraint was created by private parties engaged in private action, and did not result from an act of government. And in each case, the restraint continues because the parties choose to maintain it. The settlement agreement (like the co-promotion agreement and the back-up manufacturing agreement) was not contingent on this Court's entry of a consent judgment. (¶ 80.) Just as with Watson, Par/Paddock's anticompetitive agreement with Solvay became effective independent of any court action.

Noerr does not immunize parties simply because, after they agree to restrain their marketplace behavior, they then ask the government to adopt or enforce the

restraint. *See, e.g., Columbia Steel Casting Co., Inc. v. Portland Gen. Elec. Co.*, 111 F.3d 1427, 1446 (9th Cir. 1996) (finding no *Noerr* protection where utility entered into a market division agreement and then obtained an order from a state agency, noting that "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"); *Premier Elec. Constr. Co. v. Nat'l Elec. Contractors Ass'n*, 814 F.2d 358 (7th Cir. 1987) (agreement between union and trade association to fix prices was not immunized by lawsuit to enforce the agreement). The Eleventh Circuit's decision in *McGuire Oil Co. v. Mapco, Inc.*, 958 F.2d 1552, 1561 (11th Cir. 1992), articulates this same principle. In holding that the antitrust defendant's pursuit of litigation (along with threats to institute litigation) was *Noerr*-protected, the court distinguished *Premier* on the ground that the case before it, unlike *Premier*, did not involve any non-petitioning, "predicate act" that constituted an independent antitrust violation. *Id.*

B. The cause of the harm in this case is private, not governmental, action

Once entered, the consent judgment did not become the cause of the anticompetitive harm. On its face, the consent judgment leaves the parties with control over the date Par/Paddock can market generic AndroGel. Paragraph 10 broadly enjoins Par and Paddock from marketing the Paddock product, but this injunction is limited by the phrase "[e]xcept as agreed to by the parties pursuant to the

Agreements in settlement of this Litigation or otherwise." (Ex. 5 at 5.) Thus, under the terms of Paragraph 10, the parties may modify the date of Par/Paddock's entry, without any action by this Court, simply by agreeing on a different entry date. The parties also control the limitations in Paragraph 6. That paragraph provides that Par/Paddock is permitted to enter before 2015 if "any Generic Testosterone Gel Product (as defined in the relevant Agreements)" is offered for sale. (Ex. 5 at 4.) The parties can simply agree that Solvay will trigger this early entry provision, which it can accomplish either by marketing generic AndroGel itself or by authorizing Watson or some other company to do so.

Thus, Par and Paddock misstate the facts when they claim that the consent judgment is what precludes their sale of a generic AndroGel product. In fact, the parties crafted a stipulated injunction that effectively maintains their private control over the generic entry limitation. In other words, there is no "'intervening government action [that] breaks the causal chain.'" (Par's Mot. at 8 (quoting *Andrx v. Biovail*, 256 F.3d at 818).) Nor can they plausibly claim that they are merely "abiding by the court's order." (Par's Mot. at 8.)

Par and Paddock try to bolster their claim to *Noerr* protection by pointing out that a consent judgment can accomplish certain results that cannot be achieved through a private agreement – such as maintaining the court's jurisdiction to enforce

the settlement. (Par's Mot. at 5, 6.) But those additional "security" benefits (*see* Par's Mot. at 4) have no antitrust significance here. They plainly do not cause the competitive harm. Par and Paddock created an unlawful restraint when they agreed to abandon their patent challenge in return for a share of Solvay's monopoly profits and the restraint remains under defendants' joint control. That they later obtained the ability to ask this Court to enforce their agreement does not change that basic fact.

Given the facts here, Par/Paddock's extensive discussion (Par's Mot. at 8-15) of the unpublished district court decision in *MedImmune v. Genentech*, No. 03-2567, 2003 WL 25550611 (C.D. Cal. Dec. 23, 2003), is irrelevant. *MedImmune* addressed a consent judgment reversing a decision of the Patent and Trademark Office awarding priority in a patent interference proceeding. In a subsequent antitrust case brought by MedImmune, the court held that the parties to the settlement were shielded by the *Noerr* doctrine, because (unlike here) "the very anticompetitiveness of the [settlement] agreement depends on the government exercising its discretion to create an anticompetitive result." *Id*. at *6. The anticompetitive harm to MedImmune required both the court's overturning the PTO's priority determination and the PTO's issuance of the new patent. *Id*. at *5. Overturning the PTO's priority decision, the court said, could not be accomplished by private agreement – "there was simply no non-petitioning means for priority to be resolved." *Id.* at *6. In this case, in contrast, the

parties not only *could*, they *did*, achieve an anticompetitive result without regard to the outcome of their request for entry of the consent judgment.

In sum, because the challenged restraint here is not "the result of valid government action," *Allied Tube & Conduit Corp. v. Indian Head, Inc*., 486 U.S. 492, 499 (1988), Par and Paddock cannot rely on the principle that those urging the government to take anticompetitive action enjoy antitrust immunity.

C. Defendants' failure to disclose to the Court the terms of their agreement is an independent ground to reject their *Noerr* argument

Par and Paddock have little to say about *In re Ciprofloxacin Hydrochloride Antitrust Litigation (Cipro I)*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003), which rejected the very same type of *Noerr* argument that they assert here. The *Cipro I* defendants claimed that their conduct was shielded by the *Noerr* doctrine because a consent judgment barred the generic challenger from selling its product until the patent expired. *Id.* at 196. The court found this argument "easily refuted," because neither the challenged agreements nor their terms were submitted to the court. *Id.* at 212. As a result, the judge who signed the consent judgment could not have considered, adopted, or approved the defendants' private agreements, making it inappropriate to attribute the restraint to court action. *Id*. at 212-13.

The fact that this Court never approved (or even saw) the very terms that the Complaint alleges produced an anticompetitive settlement (SAC ¶ 80) – one based on the sharing of monopoly profits rather than the arms-length negotiations that are presumed to occur – likewise makes Par/Paddock's *Noerr* argument untenable. Indeed, Par/Paddock's *Noerr* argument relies on the proposition that a judge signing a consent judgment necessarily determines that the settlement agreement embodied in the decree is fair, lawful, and does not harm third parties. (Par's Mot. at 14.) But how could the Court have made that assessment of the settlement without knowing its material terms?

Par/Paddock's assertion that Eleventh Circuit precedent makes Solvay's payments to the generics "irrelevant" (Par's Mot. at 15-16) cannot save their *Noerr* argument. This contention simply conflates their immunity claim under *Noerr* with their defense to the substantive violation. Moreover, any suggestion that the Court was legally precluded from considering Solvay's payments to the generics in assessing whether the decree was fair and reasonable contradicts Par/Paddock's assertion that the Court had discretion to reject their request for a consent judgment.

D. Defendants' request for entry of the consent judgment should not be deemed petitioning

Accepting Par/Paddock's *Noerr* argument would also require this Court to find that their request for entry of the consent judgment amounts to "petitioning."[35] The Court should decline to do so. The decision on which Par and Paddock rely, the district court opinion in *MedImmune*, treated such a request as petitioning, but its rationale (the need for court action to overturn the PTO's priority decision) does not apply here. Furthermore, a court's role in entering a consent judgment differs fundamentally from its role when parties invoke the adjudicatory process to petition. *See, e.g.*, *Local Number 93 v. City of Cleveland*, 478 U.S. 501, 522 (1986) ("[I]t is the agreement of the parties, rather than the force of the law upon which the complaint was originally based, that creates the obligations embodied in the consent decree."). Consideration of the distinct role of governmental decision-making through courts is critical, for the Supreme Court has made it clear that the scope of *Noerr* protection depends on "the source, context, and nature of the anticompetitive restraint at issue." *Allied Tube*, 486 U.S. at 499 (1988). Moreover, the Court recognized in *Broadcast*

[35] The FTC's Complaint challenges Par/Paddock's private agreement with Solvay to refrain from competing in return for compensation – not the parties' request that this Court enter the consent judgment. As explained above, Par and Paddock's claim to *Noerr* immunity is essentially an erroneous "causation" argument.

Music, Inc. v. Columbia Broadcasting System, Inc., 441 U.S. 1, 13 (1978), that "a consent judgment, even one entered at the behest of the Antitrust Division, does not immunize the defendant from liability for actions, including those contemplated by the decree, that violate the rights of non parties." The Federal Circuit did not adopt the *MedImmune* district court's *Noerr* analysis[36] (nor, to our knowledge, has any court), and neither should this Court.

* * *

In the end, Par/Paddock's various arguments for *Noerr* protection prove too much. For if the claim that *Noerr* requires dismissal here were accepted, then litigants would be free to include all manner of private anticompetitive agreements in their private settlements and shield those agreements from antitrust scrutiny as long as a judge signs a consent judgment. Such a result would stretch *Noerr*'s protection of "mere attempts to influence the passage or enforcement of laws" beyond all recognition. *Noerr*, 365 U.S. at 135.

[36] On appeal, the Federal Circuit decided "it was unnecessary for the district court to have relied on *Noerr-Pennington* immunity" to resolve the plaintiff's antitrust claim. *MedImmune v. Genentech*, 427 F.3d 958, 967 (Fed. Cir. 2005), *rev'd on other grounds*, 549 U.S. 118 (2007).

CONCLUSION

For the foregoing reasons, defendants' motions to dismiss should be denied.

Respectfully submitted this 21st day of August, 2009.

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L.R. 7.1 (D) Certificate of Font Compliance

I hereby certify that the foregoing has been prepared with one of the font and point selections approved by the Court in Local Rule 5.1 (C), Northern District of Georgia, specifically Times New Roman 14 point.

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