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

FEDERAL TRADE COMMISSION, Plaintiff, v. WATSON PHARMACEUTICALS, INC., et al. Defendants.	Case No. 1:09-cv-00955-TWT

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS PAR PHARMACEUTICAL COMPANIES, INC. AND PADDOCK LABORATORIES, INC.'S MOTION TO DISMISS THE SECOND AMENDED COMPLAINT

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STATUTES

The FTC's claims against Par and Paddock should be dismissed with prejudice under this Circuit's undisputedly binding precedent for the reasons detailed in the motion to dismiss filed by Par/Paddock's co-Defendants Solvay and Watson, which apply to both of the patent settlements at issue.[1] Par/Paddock file separately, however, because in addition to this Circuit's binding precedent on patent settlements, there are two bases for dismissal that apply only to the settlement between Solvay and Par/Paddock.

First, unlike the Watson settlement, which ended that separate patent litigation pursuant to a voluntary stipulation of dismissal under Rule 41(a) of the Federal Rules of Civil Procedure, Solvay and Par/Paddock petitioned this Court for a Consent Judgment and Order of Permanent Injunction (the "2006 Order") (Exhibit A), which not only resolved the separate patent litigation between Solvay and Par/Paddock but also had prospective force of law enjoining and estopping generic marketing by Par/Paddock until 2015 (i.e., five years prior to expiration of

[1] *See Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1064, 1075 (11th Cir. 2005) (holding patent settlements, accompanied by alleged "reverse payments," lawful as long as any alleged restraint on generic entry is "no more broad than the patent's own exclusionary power"); *see also Andrx Pharms., Inc. v. Elan Corp., PLC*, 421 F.3d 1227, 1235 (11th Cir. 2005) (discussing that patent settlements are lawful so long as they do not exceed the "scope of the exclusionary potential of the patent"); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003) (holding patent settlements not subject to "traditional antitrust analysis" so long as terms remain within exclusionary rights of patent).

Solvay's patent). As detailed herein, under the *Noerr-Pennington* doctrine, the parties to the 2006 Order are *immune* from antitrust liability for any alleged anticompetitive effects from the court-ordered restraint on Par/Paddock's generic entry.

Second, even assuming *arguendo* that the FTC could state a claim as to the Watson settlement, the FTC still would *not* be able to do so as to the Par/Paddock settlement because, as detailed herein, the FTC fails to make any plausible allegation of competitive harm from *second* ANDA filer Par/Paddock coming to market at the *same time* as the *first filer*, Watson.

Given the FTC's avowed policy of bringing patent-settlement cases as vehicles for Supreme Court review to *overturn this Circuit's precedent* (*see, e.g.*, Solvay/Watson Mot. at 5-8), Par/Paddock respectfully request that if the Court dismisses the FTC's claims against Par/Paddock under *Schering-Plough* and this Circuit's other patent-settlement precedents, the Court nonetheless reach Par/Paddock's *Noerr-Pennington* and lack-of-competitive-harm arguments, either of which would serve as an independent ground for dismissal of Par/Paddock.

After nearly three years of defending the Par/Paddock settlement against the FTC (and now the follow-on private cases), Par/Paddock respectfully seek some modicum of repose and to avoid the FTC's misadventures in *certiorari* to undo the

law of this Circuit (particularly when that law has been followed by the Second and Federal Circuits, *see, e.g.*, Solvay/Watson Mot. at 14, the only other circuits that have ruled on the antitrust analysis of final patent settlements).

STANDARD OF REVIEW

In reviewing a motion to dismiss, the Court must accept the complaint's material allegations of fact. *Glover v. Liggett Group, Inc.*, 459 F.3d 1304, 1308 (11th Cir. 2006). Nonetheless, where, as here, there are particularly complex antitrust claims, the motion should be granted if the plaintiff fails to plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

I. THE ALLEGED RESTRAINT ON PAR/PADDOCK'S GENERIC ENTRY DERIVES FROM THIS COURT'S 2006 ORDER AND, THEREFORE, IS IMMUNE FROM ANTITRUST LIABILITY UNDER THE *NOERR-PENNINGTON* DOCTRINE.

The FTC's allegations against the Par/Paddock settlement fail as a matter of law because the *Noerr-Pennington* doctrine absolutely immunizes the parties to the Court's 2006 Order from antitrust liability for court-ordered restraints on generic entry. The *Noerr-Pennington* doctrine provides antitrust immunity for First Amendment petitioning activity, including petitioning the courts.[2] Under *Noerr-*

[2] *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670 (1965);

Pennington, "the federal anti-trust laws do not regulate the conduct of private individuals in seeking anti-competitive action from the government." *City of Columbia v. Omni Outdoor Adver., Inc.*, 499 U.S. 365, 379-80 (1991), *quoted in McGuire Oil Co. v. Mapco, Inc.*, 958 F.2d 1552, 1558 (11th Cir. 1992). Thus, "[w]hen a restraint on trade 'is the result of valid governmental action, as opposed to private action, those urging the governmental action enjoy absolute immunity from antitrust liability for the anticompetitive restraint.'" *Mun. Utilities Bd. v. Ala. Power Co.*, 934 F.2d 1493, 1505 (11th Cir. 1991) (quoting *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988)).

Because Solvay and Par/Paddock petitioned this Court for the 2006 Order, which not only terminated that patent litigation but also enjoined Par/Paddock's generic entry and estopped Par/Paddock from further challenge to Solvay's patent, the parties are absolutely immune from antitrust liability for any alleged anticompetitive effects flowing from or incidental to the restraints in that court order. *See TEC Cogeneration Inc. v. Fla. Power & Light Co.*, 76 F.3d 1560, 1572 (11th Cir. 1996) (explaining that *Noerr-Pennington* confers "absolute immunity" where allegedly anticompetitive effect is the "result of valid governmental action" or "'incidental' to a valid effort to influence governmental action").

Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 510-11 (1972) (extending *Noerr-Pennington* immunity to petitioning the courts).

A. Solvay and Par/Paddock Petitioned This Court for the 2006 Order That Bars Par/Paddock's Entry.

After three years of costly patent litigation, Solvay and Par/Paddock agreed to settle by permitting Par/Paddock to market a generic version of AndroGel approximately five years prior to patent expiration. SAC ¶ 76. To achieve finality and certainty, Solvay and Par/Paddock petitioned the Court for a judgment and order of permanent injunction. *See, e.g.*, *Stovall v. City of Cocoa*, 117 F.3d 1238, 1242 (11th Cir. 1997) ("[T]he consent decree does not merely validate a compromise but, *by virtue of its injunctive provisions*, reaches into the future and has continuing effect . . . .") (emphasis added); *SEC v. Randolph*, 736 F.2d 525, 528 (9th Cir. 1984) ("A consent decree offers more security to the parties than a settlement agreement where the only penalty for failure to abide by the agreement is another suit."). Indeed, to provide complete certainty for the settlement, Par, which had been Paddock's ANDA partner but not a party to the litigation, consented to the jurisdiction of this Court in the 2006 Order. Ex. A at 3.

Thus, in contrast to the Rule 41(a) voluntary stipulation of dismissal that effectuated the Watson settlement (Ex. B), Solvay and Par/Paddock petitioned this Court for an order terminating their litigation, enjoining Par/Paddock's market entry, and estopping Par/Paddock from subsequently challenging the patent.

Consistent with *Schering-Plough* and this Circuit's other patent-settlement

precedents, the 2006 Order provides, for example, that the settlement "will facilitate competition and the benefits therefrom approximately five years earlier than could be achieved if the Paddock Product were permanently enjoined during the life of the '894 patent." Ex. A at 3. Similarly, the 2006 Order describes the Par/Paddock settlement as a "good faith final settlement agreement regarding this Litigation," noting further that the settlement "was encouraged by the Court pursuant to its Local Rules . . . ." Ex. A at 2. Furthermore, "Paddock and Par are barred from practicing the '894 Patent" and "enjoined and estopped during the term of the '894 Patent, from making any challenge to the validity or enforceability of the '894 Patent with respect to the claims asserted against Paddock, or from marketing and selling the Paddock Product." Ex. A ¶¶ 6, 10.

Thus, through their successful petitioning, Solvay and Par/Paddock resolved their patent dispute with the certainty and legal permanence that only a court order, i.e., governmental action, could provide.[3] The 2006 Order "accomplished

[3] *E.g.*, *Rowe v. Jones*, 483 F.3d 791, 797 (11th Cir. 2007) ("[B]ecause consent decrees are entered by the court and are judicially enforceable, they function like any other court order or judgment and thus may be enforced by judicial sanctions, including citation for contempt if [they are] violated."); *cf. Schering-Plough*, 402 F.3d at 1072 (noting when vacating the FTC's antitrust decision against patent settlements: "[T]he Commission's opinion would leave settlements, *including those endorsed and facilitated by a federal court*, with little confidence. The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits.") (emphasis added).

results . . . that could not have been accomplished through private agreement." *MedImmune, Inc. v. Genentech, Inc.*, No. 03-2567, 2003 WL 25550611, at *7 (C.D. Cal. Dec. 23, 2003) (Pfaelzer, J.) (immunizing parties from antitrust liability under *Noerr-Pennington* because allegedly anticompetitive patent settlement was effectuated by consent judgment).

Accordingly, the FTC's allegations against the Par/Paddock settlement are foreclosed under *Noerr-Pennington* because the restraint on Par/Paddock's generic entry that the FTC alleges is the competitive harm (*e.g.*, SAC ¶¶ 94-98) derives from the 2006 Order. While the FTC alleges that business arrangements with Solvay induced Par/Paddock's "delayed" market entry (SAC ¶¶ 6, 73-74, 78-79), the purported restraint on competition is the allegedly "delayed" generic entry. *See Valley Drug*, 344 F.3d at 1309 ("The failure to produce the competing [generic] drug, rather than the payment of money, is the exclusionary effect . . . .").

Because Par/Paddock's allegedly delayed entry results from a court order setting forth the terms enjoining Par/Paddock's generic entry and estopping further challenge to Solvay's patent (Ex. A at 4-5), the anticompetitive effects alleged by the FTC flow from and are incidental to governmental action.

B. *Noerr-Pennington* Immunizes Solvay and Par/Paddock for Any Alleged Anticompetitive Effects from the 2006 Order.

The *Noerr-Pennington* doctrine immunizes private parties for the results

achieved in court-ordered consent judgments. Here, Solvay and Par/Paddock successfully petitioned this Court for the 2006 Order. Accordingly, *Noerr-Pennington* immunizes the parties from antitrust liability for both petitioning for the governmental action and abiding by the court's order. *E.g.*, *TEC Cogeneration*, 76 F.3d at 1572 (11th Cir. 1996) (holding *Noerr-Pennington* applicable where anticompetitive effects flow from or are incidental to "a valid effort to influence governmental action"); *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 818 (D.C. Cir. 2001) ("If anticompetitive harm is caused by the decision of a court, even though granted at the request of a private party, no private restraint of trade occurs because the intervening government action breaks the causal chain.").[4]

The holding in *MedImmune, Inc. v. Genentech, Inc.*, No. 03-2567, 2003 WL 25550611 (C.D. Cal. Dec. 23, 2003) (Pfaelzer, J.), a case with similar allegations, illustrates how *Noerr-Pennington* and their progeny require immunity for any anticompetitive effects flowing from a court-ordered consent judgment. In *MedImmune*, two biotechnology companies, Genentech and Celltech, held patents claiming certain DNA technology. *Id.* at *1. Genentech advised the PTO of the

[4] *See also Cal. Motor Transport*, 404 U.S. at 510-11 ("[I]t would be destructive of rights of association and petition to hold that groups with common interests may not, without violating the antitrust laws, use the channels and procedures of state and federal . . . courts to advocate their causes and points of view respecting resolution of their business and economic interests *vis-à-vis* their competitors."), *quoted in McGuire Oil*, 958 F.2d at 1559 (11th Cir. 1992).

patent conflict. *Id.* The PTO declared patent interference and awarded priority to Celltech. *Id.* Genentech appealed the PTO's determination to the U.S. District Court for the Northern District of California, assigned to Judge Chesney. *Id.* at *2.

After Judge Chesney denied summary judgment because disputed issues of fact existed as to priority, Judge Chesney suggested mediation. *Id.* The mediation succeeded, and the parties agreed that Celltech cede its patent priority to Genentech (i.e., the opposite outcome from the PTO). *Id.* The parties also entered into a contemporaneous business transaction, the Amended and Restated License Agreement (or "ARLA"), in which Genentech agreed to pay royalties to Celltech based on Genentech's income from its newly prioritized patent, thereby splitting Genentech's newfound monopoly rents with its former patent adversary, Celltech. *Id.* at *2, *10. The parties subsequently petitioned Judge Chesney for a consent judgment effectuating the settlement, and Judge Chesney issued an "Order and Judgment" resolving the patent-priority dispute in favor of Genentech. *Id.* at *2.

Subsequently, MedImmune, another biotechnology company, filed an antitrust suit against the settlement, claiming that "Celltech and Genentech illegally resolved the priority dispute between them in a manner that required neither Celltech nor Genentech to give up anything, but that was designed to cause a real loss to others in the industry." *Id.* at *1. Specifically, MedImmune alleged that the

defendants' settlement arrangements "had the effect of creating a 29-year patent monopoly" over the DNA technology. *Id.* Celltech and Genentech countered that *Noerr-Pennington* immunized them from antitrust liability because their settlement was effectuated by a consent judgment. *Id.* at *3.

The court presiding over the antitrust claims first addressed plaintiff's argument that "priority *could* have been resolved without government action and that *Noerr-Pennington* immunity does not attach simply because the Defendants chose to resolve priority through Judge Chesney's Court." *Id.* at *5. The court explained that plaintiff "has failed to cite, and this Court has been unable to find, any law to support the proposition that immunity is unavailable if the anticompetitive result *could* have occurred without government action, even though the result does not actually occur that way." *Id.* The court continued, "'where a restraint upon trade or monopolization is the result of valid governmental action, as opposed to private action, those urging the governmental action enjoy absolute immunity from antitrust liability . . . .'" *Id.* (quoting *Allied Tube*, 486 U.S. at 499). The court concluded, "[t]he antitrust immunity that the government enjoys, and that petitioners who urge government action correspondingly enjoy, is not dependent on there being a non-governmental way to have achieved the anti-competitive result; it depends simply on whether the alleged

violation actually involved petitioning." *MedImmune*, at *5; *see also TEC Cogeneration*, 76 F.3d at 1570 (11th Cir. 1996) ("[C]oncerted efforts to restrain or monopolize trade by petitioning government officials are protected from antitrust liability under the Sherman Act.").

The court next addressed plaintiff's argument that a consent judgment is insufficient to confer *Noerr-Pennington* immunity. The court noted that "settlements that merely require compulsory filings, ministerial agency actions, or inconsequential court orders such as Rule 41(a) dismissals do not raise a *Noerr-Pennington* defense." *MedImmune*, at *6.[5] But the court distinguished settlement agreements entered by consent judgment because "the very anti-competitiveness of the agreement depends on the government exercising its discretion to create an anti-competitive result." *MedImmune*, at *6; *see also Mun. Utilities*, 934 F.2d at 1505 (11th Cir. 1991) (holding that *Noerr-Pennington* attaches where anticompetitive effects are the "result of valid governmental action"). The court

[5] *Cf. Andrx*, 256 F.3d at 803, 818-19 (D.C. Cir. 2001) (declining to apply *Noerr-Pennington* to private agreement never presented to or approved by court and that did not settle the litigation at issue); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 196-97, 212-13 (E.D.N.Y. 2003) (holding *Noerr-Pennington* inapplicable where the court did not learn of the parties' settlement terms, including that generic would not enter during life of the patent, until after signing the consent judgment); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 635 (E.D. Mich. 2000) (refusing to apply *Noerr-Pennington* to "purely private" agreement that was "not filed with, presented to, or approved by the court presiding over th[e] litigation" and that "settled none of the infringement claims").

emphasized that: "Defendants in this case did not merely present their settlement to Judge Chesney for approval; they sought a Judgment and an Order as well. The documents that she signed accomplished results, such as overturning the Board's priority decision, that could not have been accomplished through private agreement." *MedImmune*, at *7.

The court next considered plaintiff's argument that *Noerr-Pennington* applies to a consent judgment only if the judge made a "considered, substantive judgment." *Id.* The court held: "It does not matter whether Judge Chesney ever reached a 'considered, substantive judgment' (to use MedImmune's phrase), that Genentech deserved priority. To evaluate this question would require deconstructing the decision-making process . . . ." *Id.* The court reasoned that whether the judge "made a 'considered, substantive' judgment has not been evaluated in prior cases applying *Noerr*, and this Court declines to add that requirement to the *Noerr-Pennington* doctrine. It does not matter how or why Judge Chesney reached her decision. It matters only that she had the discretion to resolve priority in favor of Genentech and she did so." *Id.*

The court thus held that *Noerr-Pennington* immunized defendants from antitrust liability because the alleged anticompetitive effects resulted from court action. *Id.* at *11; *see also Allied Tube*, 486 U.S. at 499 ("Concerted efforts to

restrain or monopolize trade by petitioning government officials are protected from antitrust liability under the doctrine established by *Noerr*."); *McGuire Oil*, 958 F.2d at 1560 n.11 (11th Cir. 1992) ("[Using] the adjudicatory process to obtain a favorable outcome . . . is protected under the *Noerr-Pennington* doctrine . . . .").

The outcome compelled in *MedImmune* by *Noerr-Pennington* and their progeny is instructive here. First, it is irrelevant whether Solvay and Par/Paddock could have achieved the results they sought from this Court by non-governmental means. *See MedImmune*, at *6 ("No law supports MedImmune's contention that *Noerr-Pennington* immunity does not attach to petitioning if the petitioner's desired result could have been accomplished through means not involving petitioning."). At all events, as discussed *supra* at 5-7, a private settlement agreement and mere voluntary dismissal would have been incapable of achieving the certainty and legal permanence of the 2006 Order. Only the court could enjoin Par/Paddock's generic entry and estop further challenge to Solvay's patent.

Second, as in *MedImmune*, Solvay and Par/Paddock did not merely seek "approval" for their settlement, but a "judgment and an order" completely resolving the litigation and enjoining future conduct. *MedImmune*, at *7. The 2006 Order is what precludes Par/Paddock's generic entry, and that restraint is the anticompetitive harm alleged in the Complaint. *E.g.*, SAC ¶¶ 94-98; *see also*

Valley Drug, 344 F.3d at 1309 ("The failure to produce the competing [generic] drug, rather than the payment of money, is the exclusionary effect . . . .").

Third, like the consent judgment in *MedImmune*, the 2006 Order was discretionary. Consent judgments are not automatic, but instead require judicial evaluation of the public's interest and the agreement's fairness and lawfulness. *E.g.*, *Stovall*, 117 F.3d at 1244 (11th Cir. 1997) ("In deciding whether to approve a consent decree, the district court must evaluate whether the decree is fair, reasonable, and lawful."); *see also SmithKline Beecham Corp. v. Pentech Pharms., Inc.*, 261 F. Supp. 2d 1002, 1008 (N.D. Ill. 2003) (Posner, J., sitting by designation) ("It is not as if the [Rule 41(a)] settlement agreement were embodied in a consent decree. Such a decree is judicially enforceable and the judge in issuing it must determine that it does not offend public policy, as by harming third parties, before he can approve it.").

The FTC's allegation that the 2006 Order did not approve the parties' contemporaneous business transactions, (SAC ¶ 80), is irrelevant to the *Noerr-Pennington* analysis. Notably, the settlement in *MedImmune* also occurred contemporaneous with a business arrangement, and the court still applied *Noerr-Pennington* to the results the parties obtained by petitioning for the consent judgment. There, on the same day that Celltech and Genentech reached the

settlement agreement in which Celltech ceded patent priority to Genentech, the parties also entered into the Amended and Restated License Agreement, in which Genentech agreed to split with Celltech the royalties Genentech would receive from licensing its newly prioritized patent. *MedImmune*, at *2, *10. Plaintiff alleged that the settlement and royalty agreements amounted to an anticompetitive attempt to extend the patent's life. But the contemporaneous business arrangement was not relevant to the court's *Noerr-Pennington* analysis and did not preclude the court's application of *Noerr-Pennington* immunity to the parties' settlement achieved in the consent judgment. *Id.* at *3-8.

At all events, here, the 2006 Order was entered under this Circuit's precedents, which hold that contemporaneous business transactions are irrelevant to patent settlements so long as the settlement does not restrict competition beyond the exclusionary potential of the patent. *E.g.*, *Schering-Plough*, 402 F.3d at 1064, 1075-76; *Valley Drug*, 344 F.3d at 1309. In this Circuit, patent settlements exceed the exclusionary potential of the patent *only if*: (i) the agreement delays generic entry beyond the patent term; (ii) the agreement restrains market entry of unrelated or non-infringing products; (iii) the patent was obtained by fraud; or (iv) the patent litigation was a sham. *Schering-Plough*, 402 F.3d at 1068, 1073; *Valley Drug*, 344 F.3d at 1306 n.18, 1307 n.19, 1312.

The terms of the 2006 Order demonstrate that none of these conditions was present. Ex. A at 2-5. Indeed, even the FTC does not allege (nor could it) that any of these conditions exist. Accordingly, it is irrelevant that the 2006 Order did not approve Solvay and Par/Paddock's contemporaneous business transactions. *Cf. MedImmune*, at *8 ("Trial judges are presumed to know the law and to apply it in making their decisions.") (quoting *Walton v. Arizona*, 497 U.S. 639, 653 (1990)) (internal quotation marks omitted).

II. THE COMPLAINT FAILS TO STATE A CLAIM AGAINST PAR/PADDOCK BECAUSE THERE ARE NO PLAUSIBLE ALLEGATIONS OF HARM TO COMPETITION FROM PAR/PADDOCK AS THE SECOND ANDA FILER ENTERING AT THE SAME TIME AS WATSON, THE FIRST ANDA FILER.

Given the allegations here and the Hatch-Waxman regulatory regime that blocks subsequent ANDA filers from market entry until *after* first ANDA filers have had an opportunity to enjoy 180 days of generic marketing exclusivity, the FTC cannot state a plausible antitrust claim against the Par/Paddock settlement because Par/Paddock as the second ANDA filer obtaining the same 2015 entry date as first ANDA filer Watson cannot harm competition.[6]

[6] *See, e.g., Levine v. Cent. Fla. Med. Affiliates, Inc.*, 72 F.3d 1538, 1545 (11th Cir. 1996) ("[T]he absence of any threat to competition means that no [antitrust] violation has occurred and that even suit by the government—which enjoys automatic standing—must be dismissed."); *see also Valley Drug*, 344 F.3d at 1303-04 ("[T]he ultimate purpose of the antitrust inquiry is to form a judgment with respect to the competitive significance of the restraint at issue.").

A. Congress Designed the Hatch-Waxman Regulatory Scheme to Prevent Subsequent ANDA Filers from Entering at the Same Time as First Filers—Much Less Earlier than the First Filer.

"The Hatch-Waxman Amendments create a strong incentive for a generic competitor to be the first to file an ANDA and receive FDA approval: a 180-day period of marketing exclusivity vis-à-vis other generic competitors. In other words, the first filer to receive FDA approval is entitled to market the generic versions of the drug for 180 days without competition from any other generic drug manufacturers." *Valley Drug Co. v. Geneva Pharms., Inc.*, 350 F.3d 1181, 1185 n.10 (11th Cir. 2003). This reward for first filers is a *barrier to entry* by subsequent ANDA filers, who cannot receive final FDA approval until the expiration of a first filer's 180-day exclusivity period. 21 U.S.C. § 355(j)(5)(B)(iv) (2000); SAC ¶ 23 ("The Hatch-Waxman Act gives the first generic company filing an ANDA . . . a period of protection from competition with other generic versions of the drug."). Without final FDA approval, subsequent ANDA filers cannot enter the market with their generic version of the drug. 21 U.S.C. § 355(a) (2000); *Schering-Plough*, 402 F.3d at 1059 n.2 ("The FDA must approve any new drug before it can be marketed or sold in the United States.").

The FTC admits at SAC ¶ 23 that the ANDAs here issued before the effective date of the Medicare Prescription Drug, Improvement, and Modernization

Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003) ("MMA"). Prior to the 180-day exclusivity forfeiture provisions in the MMA, to avoid being "parked" by a first ANDA filer's settlement with the patent holder, a subsequent ANDA filer had to prevail in a final, non-appealable decision in the patent litigation before that subsequent ANDA filer could obtain the final FDA approval necessary to come to market—and even then the subsequent filer's generic entry still would be subject to the first-filer's 180-day marketing exclusivity. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2000) (detailing FDA approval requirement); MMA, Pub. L. No. 108-173, § 1102(b)(3), 117 Stat. 2066, 2460 (Dec. 8, 2003) (codified at 21 U.S.C. § 355 note) (detailing final, non-appealable court-decision requirement for pre-MMA ANDAs).

Thus, pre-MMA, Hatch-Waxman guaranteed first ANDA filers the right to be the only generic on the market for 180 days, and, furthermore, limited subsequent ANDA filers' ability to trigger that 180-day period to a sustained, appellate court victory by the subsequent ANDA filer over the patent holder. These harsh regulatory realities discouraged subsequent ANDA filers from continuing patent challenges after a settlement by the first filer. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1073 (D.C. Cir. 1998) ("One difficulty is that the 180-day exclusivity period will seemingly always go to the *first* applicant, no

matter whose suit satisfies the court-decision trigger . . . . It seems odd to reward the first applicant if some later applicant was the party that actually prevailed in the patent-infringement litigation.").

Accordingly, this Court should not countenance an antitrust violation from Par/Paddock not entering *before* Watson as the FTC alleges (e.g., SAC ¶ 94)—when that was the result Congress intended.[7] Indeed, given that Congress designed a hierarchy of ANDA entry dates (first filers, then all subsequent filers), a second filer entering at the same time as the first filer is a *pro-competitive* outcome.

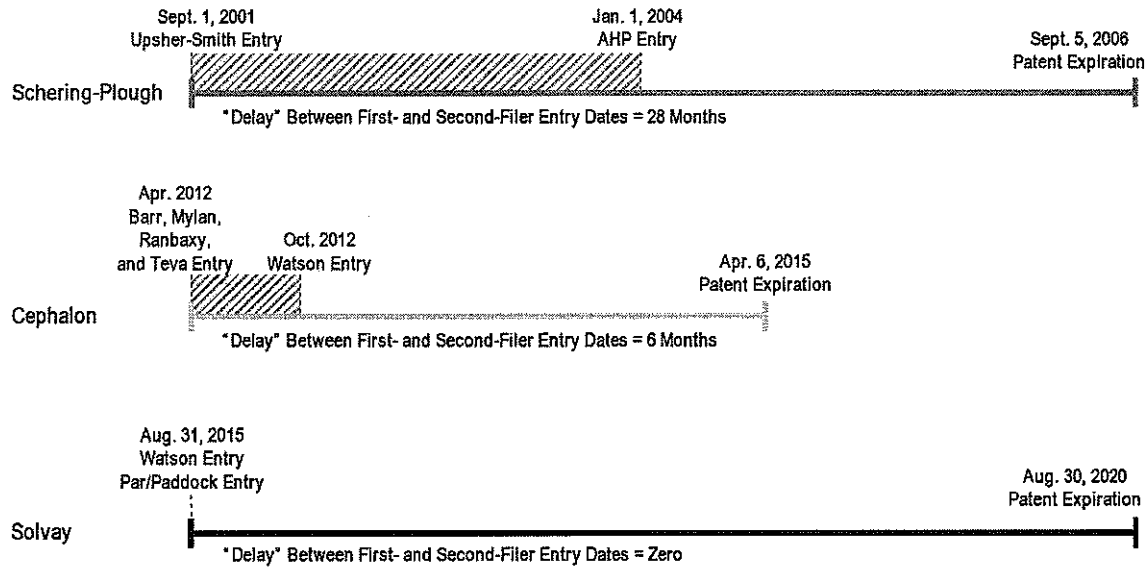
B. None of the FTC's Allegations States the Requisite Plausible Harm to Competition Arising from Second ANDA Filer Par/Paddock Entering at the Same Time as First Filer Watson.

As the FTC admits, Watson was the first ANDA filer and Solvay and Watson had agreed to the 2015 settlement entry date *before* Solvay and Par/Paddock agreed to anything. *See* SAC ¶¶ 45, 61, 71. Thus, on the allegations here, where the FTC: (i) admits that Solvay and the first filer Watson set the generic entry date (*see* SAC ¶ 61); (ii) admits that the Watson and Par/Paddock settlements are separate (*see* SAC ¶¶ 65, 76); and (iii) there is no (and can be no)

[7] *See Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 412 (2004) ("One factor of particular importance is the existence of a regulatory structure designed to deter and remedy anticompetitive harm. Where such a structure exists, the additional benefit to competition provided by antitrust enforcement will tend to be small, and it will be less plausible that the antitrust laws contemplate such additional scrutiny.").

allegation of any three-way agreement between Solvay and Watson and Par/Paddock, the FTC cannot as a matter of law show any anticompetitive "delay" or any other harm to competition from a second ANDA filer entering at the same time as the first filer.

As shown below,[8] even accepting the FTC's theory that a patent settlement providing for generic entry *prior* to patent expiry nonetheless constitutes anticompetitive "delay," the only conceivable "delay" from a second-filer settlement would be *if and only if* the second filer were to enter *after* the first filer:



[8] All of the information depicted in the figure is from public authorities of which the Court can take judicial notice on a motion to dismiss. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499, 2509 (2007).

As depicted in the figure, in the FTC's two other contested patent-settlement cases, the second ANDA filers entered *after* the first filers. First, in *In re Schering-Plough Corp.*, 136 F.T.C. 956 (2003), the second filer American Home Products ("AHP") settled with Schering-Plough for entry 28 months after the first filer Upsher-Smith's entry date. The FTC alleged harm to competition resulting from the delay between Upsher-Smith's and AHP's respective entry dates. *In re Schering-Plough Corp.*, 136 F.T.C. at 1057 ("[The] AHP agreement[] postponed availability of substantial quantities of lower-priced therapeutically equivalent drugs and thereby caused consumer injury that is readily identifiable . . . ."). Second, in *FTC v. Cephalon, Inc.*, No. 08-cv-2141-RBS (E.D. Pa.), currently pending, Watson is the second filer in that case and obtained a settlement entry date for six months after the four first filers (i.e., after the expiration of the four first filers' shared 180-day marketing exclusivity).

Here, due to Watson's waiver of 180-day exclusivity, however, second filer Par/Paddock are able to enter with generic AndroGel on the *same August 2015 date as first filer Watson*. SAC ¶¶ 65, 76. Thus, zero anticompetitive "delay" is attributable to the Par/Paddock settlement.

The FTC's attempt to allege the requisite plausible harm to competition from the Par/Paddock settlement depends on a series of but-for, hypothetical scenarios:

> Prior to their settlement, Solvay and Par/Paddock were potential competitors. By entering into their agreement, Solvay and Par/Paddock eliminated the potential that (1) Par/Paddock would have entered "at risk" and marketed generic AndroGel before a final appellate decision in the AndroGel patent litigation; (2) Par/Paddock would have prevailed in the patent litigation and marketed generic AndroGel after the litigation but well before 2015; or (3) Solvay and Par/Paddock would have agreed to settle their patent litigation on terms that did not compensate Par/Paddock, but provided for generic entry earlier than 2015.

SAC ¶ 94.

But these allegations—which are *identical* to those made one paragraph earlier against Watson—fail entirely to account for the distinction between first and subsequent ANDA filers in the Hatch-Waxman regulatory scheme and the undisputed fact that Solvay and Watson settled on the 2015 entry date without input from Par/Paddock. *See* SAC ¶¶ 60-66 (describing the Solvay-Watson negotiations with no mention of Par/Paddock). As a result, the FTC's boiler-plate, but-for allegations of harm to competition are inapposite to second filer Par/Paddock obtaining zero-delay entry on the same date as Watson.

First, as a matter of law under the Hatch-Waxman Act, Par/Paddock could *not* "have entered 'at risk' and marketed generic AndroGel before a final appellate decision in the AndroGel patent litigation," (SAC ¶ 94), because Par/Paddock had *not* received final FDA approval for Paddock's ANDA. *E.g.*, SAC ¶¶ 22-23 (no generic marketing without final FDA approval). Conspicuously, the FTC alleges

that *Watson* had received final FDA approval for Watson's first-filed ANDA and therefore could have launched at risk. SAC ¶¶ 2, 52. But there is not, nor could there be, any such allegation against second filer Par/Paddock.

Next, faced with Watson's settlement, it is implausible that second filer "Par/Paddock would have prevailed in the patent litigation and marketed generic AndroGel after the litigation but well before 2015[.]" SAC ¶ 94. Given the pre-MMA Hatch-Waxman regime (detailed *supra* at 17-19), the FTC's bare-bones allegation fails to establish the requisite plausibility under *Twombly* for the diseconomic proposition that Par/Paddock would have continued litigating the already three-year-old case after Watson settled—particularly all the way to the then-requisite final, non-appealable court decision—only for *Watson* to enjoy first-filer exclusivity with Par/Paddock dutifully waiting to enter 180 days after Watson. When a plaintiff's allegations sound in hypotheticals, those allegations need to make sense. *Twombly*, 550 U.S. at 555 ("Factual allegations must be enough to raise a right to relief above the speculative level . . . ."). Indeed, "the Supreme Court require[s] that the anticompetitive effect cannot be hypothetical or presumed. Rather, the probe must turn to 'whether the effects actually are anticompetitive.'" *Schering-Plough*, 402 F.3d at 1072 (quoting *Cal. Dental Ass'n v. FTC*, 526 U.S.

756, 775 n.12 (1999)).[9]

Finally, given Solvay and Watson's settlement for Watson's entry in 2015, it is equally implausible to allege that but-for the contemporaneous business transactions between Solvay and Par/Paddock, Solvay and Par/Paddock would have reached a settlement that "provided for generic entry earlier than 2015." SAC ¶ 94. This allegation rests on the same unprovable hypothetical that the Eleventh Circuit squarely rejected in *Schering-Plough*: "the Commission grounds its decision in the untenable supposition that without a payment there would have been different settlements . . . ." 402 F.3d at 1066 n.15. Indeed, the logic

[9] Par/Paddock made this same point in our motion to dismiss before Judge Pfaelzer just prior to her transfer order. In an attempt to plead around the point here, the FTC's SAC adds an allegation conspicuously absent from its FAC: "If Solvay had settled with Watson only, Par had ample financial incentive to continue to challenge Solvay's patent." SAC ¶ 95. The FTC apparently bases this allegation on internal projections of generic AndroGel sales that Par forecasted during the patent litigation. But those forecasts attempted to predict generic sales *assuming that Par/Paddock won the patent litigation.* The FTC does not allege (because it cannot) that those forecasts address Par/Paddock's *chances of winning* the litigation, and without a litigation-risk component the sales forecasts cannot support a conclusory allegation that Par/Paddock would have had "ample financial incentive" to continue litigating if Solvay had settled with Watson only. Furthermore, the FTC's hypotheticals ignore that even where the patent subsequently has been invalidated, this Circuit holds that parties should not have their patent settlements second-guessed: "we conclude that exposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid would undermine the patent incentives. *Patent litigation is too complex and the results too uncertain for parties to accurately forecast . . . .*" *Valley Drug*, 344 F.3d at 1308 (emphasis added).

foreclosing such "untenable supposition" in *Schering-Plough* applies with greater force here given that Solvay and Watson had settled on the 2015 entry date *before* Solvay and Par/Paddock agreed to anything. *See* SAC ¶¶ 45, 61, 71. "[P]laintiffs here have not nudged their claims across the line from conceivable to plausible," *Twombly*, 550 U.S. at 570, in alleging that Solvay would upend its negotiated entry date with Watson—for which the FTC alleges that Solvay paid dearly—by settling with Par/Paddock for an earlier date. *See* SAC ¶ 65 ("Under the parties' settlement, Watson agreed to refrain from marketing generic AndroGel until August 31, 2015, or earlier if another generic company launched a generic version of AndroGel before that date.").

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L.R. 7.1(D) Certificate of 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), specifically Times New Roman 14 point.

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