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

REPLY 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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Par/Paddock agree with the bases for dismissal under *Schering-Plough et al.* detailed in the Solvay/Watson reply, which apply to both settlements. The FTC's opposition is yet another example of the agency quarreling with this Circuit's precedent rather than working within it.[1] Remarkably, the FTC asks this Court to read these precedents *not* for what they say but for what *others* say they mean.[2] Cobbling together arguments based on *certiorari* briefs from cases the Supreme Court never took and academic writings says two things: (i) this case cannot go forward under the plain terms of this Circuit's precedents; and (ii) the FTC is girding for its next attempt to get the Supreme Court to reverse the rule first announced by this Circuit (and followed by *every court* thereafter). This is not our characterization, but the FTC's stated agenda. *See* Solvay/Watson Mot. (D.E. #130) at 6-8. Thus, we respectfully reiterate our request that even if the Court grants dismissal under *Schering-Plough et al.*, the Court also reach our *Noerr-*

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[1] *Compare* Opp'n 15 ("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."), *with Schering-Plough*, 402 F.3d at 1065 ("We think that neither the rule of reason nor the *per se* analysis is appropriate in this context. We are bound by our decision in *Valley Drug* where we held both approaches to be ill-suited . . . .").

[2] *E.g.*, Opp'n 3 ("Under the Solicitor General's reading of Eleventh Circuit precedent, the FTC's complaint states a claim."); 13 ("Under this [Areeda & Hovenkamp] standard, the FTC's complaint states valid antitrust claims, and defendants' motions should be denied.").

Pennington and second-filer arguments, which are independent grounds for dismissal. As the smallest companies in the case, we can least afford to be dragged along in an intransigeant appeal and *certiorari* battle.

I. THE FTC FAILS TO PLAUSIBLY ALLEGE ANTICOMPETITIVE "DELAY" OR ANY OTHER HARM TO COMPETITION FROM SECOND ANDA FILER, PAR/PADDOCK, ENTERING AT THE SAME TIME AS FIRST FILER, WATSON.[3]

The FTC ignores pages 17-19 of our motion, and the Hatch-Waxman provisions and cases cited therein, which demonstrate that Congress intended to *prevent* subsequent ANDA filers from entering until 180 days after first filers (particularly prior to the MMA amendments on forfeiture of first filer exclusivity, which undisputedly do not apply here). These points and authorities conceded by the FTC are fatal to their case against Par/Paddock—which hinges on three hypothetical allegations that but for payments from Solvay, Par/Paddock would enter *before* Watson. *See* SAC ¶ 94.[4]

Tellingly, the FTC says: "the complaint sets forth well-pleaded factual allegations explaining why Par would have entered before 2015—*regardless of*

[3] The FTC flips the argument order in our motion. For clarity's sake, we reply in order of the opposition: second filer then *Noerr-Pennington*.

[4] The FTC also apparently concedes that under the Supreme Court's decision in *Trinko* it is "less plausible," 540 U.S. at 412, that antitrust scrutiny was intended for a competitive outcome resulting from Congress's regulatory structure (i.e., second filer not entering before first filer). *See* Mot. 19 n.7.

whether Watson settled—had it not received a share of Solvay's monopoly profits." Opp'n 32 (emphasis added). But Watson *did* settle. And it is undisputed that Solvay and Watson set the 2015 entry date with zero input from Par/Paddock and that the settlements are separate with no three-way discussions. *See* Mot. 19-20 (collecting SAC citations); *see also* SAC ¶¶ 60-66 (detailing Solvay-Watson negotiations with no mention of Par/Paddock). The FTC cannot assume away the Watson settlement and premise competitive harm on what Par/Paddock *might have* done had Watson *not* settled.[5] Equally telling, the FTC never disputes that its theory of competitive harm against Par/Paddock depends on one paragraph of hypothetical allegations. SAC ¶ 94. But those allegations repeat *verbatim* the FTC's allegations against Watson. SAC ¶ 93. How can the FTC have accounted for Congress's segregation of first and subsequent filers when the allegations of competitive harm are identical? For all these reasons, this Court should not entertain the FTC's hypotheticals about Par/Paddock entering before Watson. At all events, not one of the three hypotheticals supports a plausible claim of competitive harm.

First, it is implausible that "Par would have marketed generic AndroGel

[5] *Schering-Plough*, 402 F.3d at 1072 ("[T]he 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.'") (quoting *Cal. Dental*, 526 U.S. at 775 n.12).

before a final decision in the patent litigation [i.e., launch at risk]." Opp'n 32. As the FTC concedes, Par's forecast assumptions of launch at risk were entirely dependent on whether Watson *first* launched at risk: "A February 2006 Par forecast assumed that Watson would launch in March 2006, and Par would follow in September 2006." SAC ¶ 54. Of course, Watson never launched at risk; Watson settled. The FTC also ignores that Watson had the FDA approval necessary to launch at risk, SAC ¶¶ 2, 22-23, 52, but Par/Paddock did not. *See* Mot. 22-23. Indeed, the FTC never alleges that Par/Paddock received such approval.[6] Thus, the FTC's new argument (never alleged) that Par/Paddock *would have* launched at risk "at any time" after Watson's settlement, Opp'n 33, is incorrect as a matter of law. And this conclusory assertion is not supported by Par's forecast assumptions of launch six months *after* Watson. SAC ¶ 54. Launching six months after Watson—with the benefit of learning whether Solvay enjoined Watson's launch—is a wholly different proposition than launching alone after a Watson settlement.

Second, it is implausible that but for Par/Paddock's settlement with Solvay "Par/Paddock would have prevailed in the patent litigation and marketed generic

[6] In fact, Par/Paddock's ANDA did not receive the requisite approval until May 2007, sixteen months after Watson's approval and eight months after Watson's settlement. Letter from Gary Buehler, Director, FDA Office of Generic Drugs, to Julie Szozda, Par Pharmaceutical Cos., Inc. (May 23, 2007) (Exhibit C).

AndroGel after the litigation but well before 2015[.]" SAC ¶ 94. Given Watson's settlement, the FTC is left to allege: "If Solvay had settled with Watson only, Par had ample financial incentive to continue to challenge Solvay's patent." SAC ¶ 95. The FTC bases this allegation entirely on Par forecasts of generic AndroGel sales *assuming* that Par/Paddock won the litigation. *Id.* As detailed in our motion, however, the FTC cannot make plausible allegations about Par's financial incentives to continue litigating based on forecasts that simply *assumed victory* with no component of litigation risk. *See* Mot. 23-24 & n.9. Not surprisingly, the FTC never responds to this point. *See* Opp'n 33-34.

The FTC also ignores that under pre-MMA Hatch-Waxman, Par/Paddock only could have won entry, after Watson settled, by litigating to a final, non-appealable court victory—after which *Watson* would still reap the reward of 180-day exclusivity. *See* Mot. 23. This *statutory disincentive* to continued litigation by subsequent ANDA filers is one of the problems that Congress specifically sought to address with the MMA amendments. *See* Mot. 17-19. Thus, the FTC's hypothetical that Par/Paddock "would have prevailed in the patent litigation," SAC ¶ 94, after Watson settled, because "Par had ample financial incentive to continue," SAC ¶ 95, is at odds with Congress's decision to amend Hatch-Waxman precisely because subsequent filers did *not* have such incentive. *Cf. Ashcroft v.*

Iqbal, 129 S. Ct. 1937, 1950 (2009) ("[W]hether a complaint states a plausible claim for relief . . . requires the reviewing court to draw on its judicial experience and common sense."). The FTC "does not unlock the doors of discovery," *id.*—particularly after two years of discovery in its investigation—with an unsupported allegation of "ample financial incentives" that Congress said were lacking.[7]

Third, the FTC does not plausibly allege that on "terms that did not compensate," SAC ¶ 94, Par/Paddock would have obtained a settlement entry date earlier than 2015. Given that Solvay and Watson had settled on the 2015 entry date before Solvay and Par/Paddock agreed to anything, SAC ¶¶ 45, 61, 71, the FTC alleges no facts supporting the allegation that Par/Paddock would have obtained entry earlier than the first filer. We focused on this point, *see* Mot. 25, but the FTC ignores it. *See* Opp'n 34. Instead, the FTC attempts to assume away that Solvay and Watson set the 2015 entry date: "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." Opp'n 34. But the FTC cannot avoid dismissal with decision-tree hypotheticals. *Twombly*, 550 U.S. at 555

[7] The FTC cites a single case for the proposition that it is "not unusual" for subsequent ANDA filers to continue litigating after a first filer settlement. Opp'n 33 & n.30 (citing *Aventis Pharma* and accompanying FDA Internet citation). But that case only proves our point because there the second filer continued litigating believing that the first filer *had forfeited* its exclusivity.

("Factual allegations must be enough to raise a right to relief above the speculative level . . . ."); *Schering-Plough*, 402 F.3d at 1072 ("anticompetitive effect cannot be hypothetical or presumed").

II. *NOERR-PENNINGTON* IMMUNIZES THE PARTIES TO THE COURT'S 2006 ORDER FROM ANTITRUST LIABILITY FOR THE RESTRAINTS ON GENERIC ENTRY CAUSED BY THE ORDER.

The FTC refuses to acknowledge that the restraint on Par/Paddock's generic entry is caused by this Court's Consent Judgment and Order of Permanent Injunction ("2006 Order") (Mot. Ex. A). As the FTC would have it, the 2006 Order is some after-the-fact nullity, with no distinction between Solvay and Par/Paddock continuing to be bound by the 2006 Order versus Solvay and Watson having ended their litigation pursuant to a FRCP Rule 41(a) voluntary dismissal. *E.g.*, Opp'n 37. That view is demonstrably incorrect.

Solvay and Par/Paddock executed their settlement agreement on September 13, 2006. SAC ¶ 76.[8] That agreement did not and could not itself terminate the litigation between them, which required a court filing. One way to terminate the litigation would have been to file a voluntary dismissal under Rule 41, which

[8] Notably, in accordance with this Circuit's policy favoring patent settlements, the Par/Paddock settlement "was encouraged by the Court pursuant to its Local Rules . . . ." Ex. A at 2; *see also* Tr. of Proceedings in *Unimed Pharms. v. Paddock Labs.*, No. 1:03-cv-2503 (Feb. 26, 2004) at 13-14 (Court: "This has all the appearances of a long, complicated, expensive, difficult case. Is there anything I can do to prevent any of that from happening?").

would *not* have required court approval. That is what Solvay and Watson did. Mot. Ex. B (providing that Solvay's suit against Watson is "voluntarily dismissed without prejudice" and making no provision whatsoever regarding Watson's entry). In contrast, Solvay and Par/Paddock, pursuant to the terms of their settlement agreement, filed the proposed consent judgment, which the Court signed a day later. The 2006 Order is what ended the litigation between Solvay and Par/Paddock. Ex. A at 2 (providing that each party "acknowledge[s] there is significant risk to each of them associated with the continued prosecution of this Litigation and have consented to judgment through a final settlement . . . .").

Moreover, the 2006 Order guarantees Par/Paddock's right to entry prior to patent expiration while simultaneously guaranteeing that Par/Paddock cannot unilaterally enter before the agreed date: "Paddock and Par are barred from practicing the '894 Patent until [no later than February 28, 2016] . . . . Paddock and Par are also hereby 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 at ¶¶ 6, 10.

Absent the 2006 Order, rather than the certainty and finality provided by the Court's injunctive powers and contempt authority, Solvay and Par/Paddock would

have had to rely on additional lawsuits for breach of contract if Par/Paddock attempted to enter earlier than allowed or if Solvay asserted its patent after the agreed entry date. This critical difference between consent decrees and private agreements is widely recognized:

> If the parties agree to compose their differences by a settlement agreement . . . the only penalty for failure to abide by the agreement is another suit. . . . A consent decree, although founded on the agreement of the parties, is a judgment. It has the force of res judicata, protecting the parties from future litigation. It thus has greater finality than a compact.

United States v. City of Miami, 664 F.2d 435, 439-40 (5th Cir. 1981).[9]

We elaborated on this critical difference between consent decrees and private agreements (including three of the four cases cited here) in our motion, at 5-6 & n.3, but the FTC ignores that section of our motion and each of the authorities. The FTC's argument that the 2006 Order does not cause the alleged restraint on Par/Paddock's generic entry, Opp'n 36-41, is irreconcilable with these

[9] *See also Rowe*, 483 F.3d at 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.*") (internal quotation marks omitted); *Stovall*, 117 F.3d at 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 . . . ."); *Randolph*, 736 F.2d at 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.* A consent decree is a judgment, has the force of res judicata, and it may be enforced by judicial sanctions, including, as in this case, citations for contempt.") (internal quotation marks and citation omitted) (emphases added).

authorities. One need only compare the 2006 Order to the Watson Rule 41(a) voluntary dismissal to see the difference between governmental restraint and reliance on private agreement (e.g., Watson's entry terms are addressed only in their private agreement). *Compare* Ex. A, *with* Ex. B. It is precisely because Solvay and Par/Paddock asked the Court to impose the restraints in the 2006 Order, and the Court did so, while there was no such request or ensuing order concerning Watson, that *Noerr-Pennington* applies to one and not the other.[10]

Judge Pfaelzer in the *MedImmune* decision also recognized this important difference between consent judgments and private agreements. *MedImmune*, at *6 ("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."). Although the FTC portrays *MedImmune* as an outlier, the point derives equally from the numerous other authorities discussed above—and in our motion—but ignored by the FTC. Another case we discussed, Mot. 14, but the FTC ignores, is *SmithKline Beecham Corp. v. Pentech Pharms.*, 261 F. Supp. 2d 1002 (N.D. Ill. 2003) (Posner, J., sitting by designation):

[10] The finality and certainty provided by the Court's powers also serve this Circuit's policy in favor of patent settlements, which is not well served if further litigation is necessary to enforce private settlement agreements underlying impermanent resolutions of disputes, such as dismissals without prejudice under Rule 41(a) stipulations. *See, e.g., Valley Drug*, 344 F.3d at 1308 n.20.

> [T]he granting of a motion to dismiss under Rule 41(a)(2) does not imply judicial approval of the underlying settlement agreement. The grant of the motion implies no view of the merits of the agreement and *confers no immunities on the settling parties*. It is not as if the 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. A settlement agreement that merely motivates the dismissal of a suit is not a judicial order, and the dismissal *does not insulate it from legal challenge*.

Id. at 1008 (emphasis added) (citation omitted).

To be sure, the restraint on Par/Paddock's generic entry is the exclusionary effect at issue in this case. *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 the 2006 Order imposes that restraint at the parties' request, *Noerr-Pennington* applies. "Causation" addressed, all of the FTC's other points are readily answered.

A. The FTC cites authorities—none of which involves a court's consent decree—in which *Noerr-Pennington* did not apply because the parties entered into agreements that were *per se* unlawful and then sought, unsuccessfully, to cleanse those independently illegal acts through governmental approval.[11] Even the FTC

[11] *See Columbia Steel*, 111 F.3d at 1433, 1446 (9th Cir. 1996) (holding *Noerr* inapplicable where restraint stemmed from *per se* unlawful market-division agreement, which was never approved by the relevant agency); *Premier Elec.*, 814 F.2d at 368, 376 (7th Cir. 1987) (holding *Noerr* inapplicable where parties entered

cannot contend that the private agreements between Solvay and Par/Paddock preceding the 2006 Order were *per se* illegal. *Valley Drug*, 344 F.3d at 1311 (patent settlements "not subject to *per se* antitrust condemnation"). Thus, just as in *McGuire Oil*, there is no "'predicate act' that constituted an independent antitrust violation." Opp'n 38.

B. The FTC argues that *Noerr-Pennington* cannot apply because "the consent judgment leaves the parties with control over the date Par/Paddock can market generic AndroGel." Opp'n 38. Critically, however, each example the FTC provides thereafter is of the parties agreeing to entry *earlier* than 2015; there is no contention (nor could there be) that the terms of the 2006 Order permit the parties to postpone Par/Paddock's entry. *See* Opp'n 38-39. Thus, the FTC's argument misses the point: the 2006 Order provides Par/Paddock a guaranteed, unilateral right to enter five years prior to patent expiry, one that Solvay cannot interfere with simply by breaching the settlement agreement; likewise, Solvay is guaranteed that Par/Paddock cannot unilaterally enter earlier than 2015 merely by breaching the settlement agreement. That the parties can agree to earlier entry does not diminish their mutual reliance on the Court's injunctive powers and contempt authority.[12]

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into *per se* unlawful price-fixing contract that the parties sought, unsuccessfully, to enforce in the courts).

[12] The FTC also claims that *MedImmune* is inapplicable because, there, overturning

C. The FTC relies on *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003), for the proposition that *Noerr* cannot apply here because the Court did not approve the parties' business agreements. Opp'n 41-42. As noted, the restraint on Par/Paddock's generic entry is the exclusionary effect at issue, not the financial terms of the parties' business agreements. *Valley Drug*, 344 F.3d at 1309; *see supra* 11. Certainly, the Court saw the terms of the restraints on Par/Paddock's entry—and that such terms did not exceed the exclusionary potential of Solvay's patent—all of which is fully reflected in the 2006 Order. *See* Mot. 5-6. Those are the "material" terms.[13]

In *Cipro*, by contrast, the generic-entry terms in the parties' settlement agreement were *not* presented to the court and were *not* part of the consent

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the PTO required governmental action, while here the parties "not only *could*, they *did*, achieve an anticompetitive result" without governmental action. Opp'n 40-41. But the FTC overlooks *MedImmune*'s express rejection of the argument that *Noerr* immunity did not apply because "priority *could* have been resolved without government action . . . ." *MedImmune*, at *5. The court explained that no law supports "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.*; *see also* Mot. 10, 13.

[13] The FTC asks, "how could the Court have made that assessment of the settlement [i.e., its propriety] without knowing its material terms?" Opp'n 42. But this only illustrates that the Court saw all it needed to see. Would the FTC have had the Court evaluate the terms of the co-promotion and manufacturing agreements before the Court could enter its consent judgment? The FTC might, but it is exactly that proposition that this Circuit has squarely rejected. *Schering-Plough*, 402 F.3d at 1074 ("The Commission's inflexible compromise-without-payment theory neglects to understand that reverse payments are a natural by-product of the Hatch-Waxman process.") (internal quotation marks omitted).

judgment—and, indeed, the parties' settlement agreement did *not* provide for generic entry until after patent expiration. *See* Mot. 11 n.5; Opp'n 41. There was never any contention in *Cipro*'s very brief *Noerr* discussion that the judgment itself restrained entry—because, unlike here, it did not. Indeed, *Cipro* expressly states: "There was no mention in the Consent Judgment of . . . the agreement by Barr, HMR and Rugby not to manufacture and market a generic form of Cipro." *Cipro*, 261 F. Supp. 2d at 196. Thus, the *Cipro* consent judgment (attached as Exhibit D) did not cause, or even address, any restraint on generic entry, a fact that the FTC ignores and that renders *Cipro*'s holding inapplicable here.

D. Throughout, the FTC assumes that the parties' request for entry of the 2006 Order constituted *Noerr-Pennington* petitioning, Opp'n 37-42, which the FTC follows with a half-hearted challenge. Opp'n 43-44. The FTC concedes that *MedImmune* "treated such a request as petitioning," Opp'n 43, but then argues that *MedImmune* is not persuasive because of its subsequent history. Opp'n 44 & n.36. But the Federal Circuit held that the challenged conduct in *MedImmune* was entirely lawful and thus found it unnecessary to address *Noerr* immunity; the court in no way rejected or even questioned Judge Pfaelzer's *Noerr* analysis.[14]

[14] *See MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 967 (Fed. Cir. 2005) ("A joint communication to a court of the terms of settlement of a matter before the court . . . [is] not action[] that would be prohibited or tainted absent immunization

If the parties had not sought entry of the 2006 Order, they would not have benefited from the Court's injunctive powers and contempt authority, but would have been left to contractual remedies. *See supra* 8-11. Such a request for the invocation of the Court's powers plainly is petitioning, and none of the FTC's cited authorities—which do not even address *Noerr-Pennington* petitioning—is to the contrary.[15] Given that the FTC concedes that enforcing a patent by filing a lawsuit "enjoys antitrust immunity," Opp'n 26, it is odd for the FTC to then argue that enforcing a patent through a consent judgment, the terms of which were reviewed and approved by the Court, is somehow unprotected.[16]

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by *Noerr-Pennington*; thus, it was unnecessary for the district court to have relied on *Noerr-Pennington* immunity.").

[15] *See Local Number 93*, 478 U.S. at 504 (addressing whether consent decree is an "order" under the Civil Rights Act, nothing to do with *Noerr*); *Broad. Music*, 441 U.S. at 13 (noting that consent decree that did not mandate the action challenged as anticompetitive did not protect subsequent conduct merely "contemplated" by decree—never addressing *Noerr*); *see also A.D. Bedell Wholesale Co. v. Philip Morris Inc.*, 263 F.3d 239, 253 (3d Cir. 2001) (rejecting party's reliance on same language from *Broadcast Music* because "[t]here was no settlement agreement in *Broadcast Music*" and neither "*Broadcast Music* nor [the case on which it relied] mentioned *Noerr-Pennington* immunity").

[16] *See Schering-Plough*, 402 F.3d at 1072 ("[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."); *Valley Drug*, 344 F.3d at 1309 ("litigation is a much more costly mechanism to achieve exclusion, *both to the parties and to the public*, than is settlement.") (emphases added).

Respectfully submitted, this 11th day of September, 2009.

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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.

Respectfully submitted this 11th day of September, 2009.

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CERTIFICATE OF SERVICE

I hereby certify that I have this day electronically filed the **REPLY MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS PAR PHARMACEUTICAL COMPANIES, INC. AND PADDOCK LABORATORIES, INC.'S MOTION TO DISMISS THE SECOND AMENDED COMPLAINT AND THE L.R. 7.1(D) CERTIFICATE OF COMPLIANCE** with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filings to the following attorneys of record:

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