EXHIBIT T

JS-6

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

AVENTIS PHARMA S.A. and AVENTIS PHARMACEUTICALS, INC., Plaintiffs, v. **AMPHASTAR PHARMACEUTICALS, INC.,** Defendant.	Case Nos. 5:03-00887-MRP (PLA) [lead] 5:04-00333-MRP (PLA) **ORDER DISMISSING Amphastar's Third Amended Counterclaim**

I. BACKGROUND

On February 17, 2009, Amphastar's Second Amended Counterclaim ("SAC") was dismissed without prejudice in a detailed order ("SAC Order"). Familiarity with the SAC Order's contents is presumed.

On March 3, the Court held a hearing to determine whether Amphastar should be allowed to replead its counterclaims. Confidential information was discussed at the hearing and the transcript was sealed to protect Amphastar's competitive interests. Hearing Tr. at 5:7-9. This unsealed Order refers to the transcript and other sealed documents. However, this Order is intentionally vague as to the documents' contents so as not to disclose confidential matters.

At the hearing, Amphastar assured the Court that its situation would be materially changed within 30 days. *Id.* at 7:24-8:4. The Court expressed doubts about Amphastar's representations because, throughout the course of this nearly six-year litigation, counsel for Amphastar has repeatedly made substantially the same assurances. *Id.* at 19:9-25.

Nevertheless, the Court allowed Amphastar to replead within 21 days. Minute Order (Mar. 3, 2009). In the same Minute Order, the Court instructed Aventis not to file any motions related to such amendment until the Court had an opportunity to review it.

Amphastar filed its amendment, the Third Amended Counterclaim ("TAC"), on March 24.[1] Amphastar's situation at that time had not changed in the manner Amphastar anticipated at the hearing.[2] The Court deferred acting on the TAC until April 8—more than two weeks after the time by which Amphastar represented that its situation would change. At that time, the Court held a telephonic status conference with the parties and invited the parties to propose the next step in the litigation. Aventis proposed filing a motion to dismiss, due April 22.

On April 17, Amphastar filed a confidential status report. The report's contents strongly suggest that Amphastar's position will not, in the immediate future, change in the way that Amphastar described at the March 3 hearing. Further, as discussed below, that report bolsters much of the SAC Order's reasoning.

As agreed at the status conference, Aventis submitted its motion on April 22. Briefing concluded on May 13 (though Amphastar attempted to file a supplemental

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[1] The TAC names additional Aventis-related entities. The Court already denied Amphastar's request for leave to join these entities. Minute Order, docket no. 91 (Mar. 3, 2009).

[2] The TAC does not contain allegations related to Amphastar's argument at the hearing.

citation of authority on May 15). In the interim, the Supreme Court denied certiorari on the patent judgment in this case. 77 U.S.L.W. 3594 (U.S. 08-937 Apr. 27, 2009). As a result, only Amphastar's counterclaims await final resolution.

Having reviewed the parties' submissions, the Court determines that oral argument would not assist in disposing of the motion. The May 19, 2009 hearing in this matter is therefore taken OFF CALENDAR.

The Court takes judicial notice that, according to publicly available government documents available at the time of this Order's filing, Amphastar's situation has not changed in the way Amphastar anticipated at the March 3 hearing.

The Court now GRANTS Aventis' motion to dismiss the TAC for the reasons discussed below. The Court expresses no opinion on Aventis' other arguments for dismissal.

II.

DISCUSSION

A. Citizen petition-related conduct.

Ripeness, falsity, materiality, and reliance. The SAC does not remedy the TAC's failure to allege a *Noerr-Pennington* exception for Aventis' citizen petition-related conduct. These pleading defects were discussed at length in the SAC Order. The defects vary by potential *Noerr-Pennington* exception theory, but include (1) ripeness, SAC Order at 22:8-25; (2) falsity, *id.* at 23:26-17; (3) materiality, *id.* at 24:18-25:1; and (4) reliance. *Id.* at 25:2-11.

Causation and damages. Of the three potential *Noerr-Pennington* exception theories identified in the SAC Order, at least two require fraud. *See id.* at 22:27-23:17; 27:7-11. Thus, an exception to these theories requires causation and damages before the antitrust law can scrutinize petitioning conduct. *Id.* The causation and damages problems are profound and overlap with the substantive antitrust elements of causation and antitrust injury. Therefore, they are elaborated

in the next section. This should avoid the confusion apparently caused by the abbreviated treatment of the matter in SAC Order at 28:20-29:18.

B. Causation and antitrust injury.

To state any substantive antitrust claim, Amphastar must allege that Aventis caused it antitrust injury. To suffer antitrust injury, Amphastar must be "an actual competitor or one ready to be a competitor." SAC Order at 28:20-21 (quoting *Bourns, Inc. v. Raychem Corp.*, 331 F.3d 704, 711 (9th Cir. 2003)). In the Hatch-Waxman context, the "intent-and-preparedness" test determines whether one is "ready to be a competitor." *Id.* at 29:10-11 (citing *Andrx Pharma., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 806-09 (D.C. Cir. 2001)). Amphastar is not yet in the market. Amphastar therefore alleges that it meets the intent-and-preparedness test.

However, Amphastar is presently excluded from the market because it lacks FDA approval. This fact goes **both** to (1) whether Aventis' **citizen petitioning conduct** could have caused Amphastar injury, thereby allowing a fraud-based exception to *Noerr-Pennington* (FDA concerns unrelated to Aventis' petitioning conduct could be a supervening cause of Amphastar's lack of FDA approval, which would prevent Amphastar from pleading the causation and damages necessary for a fraud-based *Noerr-Pennington* exception), SAC Order at 26:10-11; **and** (2) whether **any** Aventis **conduct**—including conduct not related to its citizen petition—could have caused Amphastar antitrust injury (lack of FDA approval may be a supervening cause of Amphastar's alleged market exclusion, thereby undermining the substantive antitrust elements of causation and antitrust injury). SAC Order at 29:14-17.

Of course, if Amphastar could plead (1) misconduct by Aventis that (2) caused the FDA not to approve Amphastar's ANDA, then Amphastar's counterclaim might be sustainable. *Id.* at 25:25 (citing *Andrx*, 256 F.3d at 807). *See also id.* at 26:9-22.

However, the TAC and matters subject to judicial notice undermine any plausible inference that other forces acting in or on the FDA have not supervened causation by Aventis' alleged misconduct.

The TAC discloses dealings at the FDA which suggest that FDA policy decisions—and even interaction between the legislative branch and the FDA—are a material cause of Amphastar's inability to come to market. TAC ¶¶ 72-75, 77. The TAC alleges that Aventis' "sameness" arguments in the citizen petition process were "effectively rejected" by the FDA in November 2007. ¶ 72. By its own terms, then, the TAC leaves Amphastar's lack of approval from that time onward to be caused by something other than Aventis' allegedly frivolous "sameness" arguments. ¶ 72. The TAC also alleges that Amphastar's approval has been delayed, at least in part, due to a policy dialog among market actors, legislators, and regulators. *See* ¶¶ 74-75.[3]

And at the March 3 hearing, Amphastar represented that policy advocacy by parties other than Aventis has contributed to the delay. Hearing Tr. at 6:16-17. Counsel for Amphastar even stated that an internal FDA policy dispute has contributed to Amphastar's lack of approval. Hearing Tr. at 20:1-9.[4]

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[3] These allegations also strongly reinforce this Court's twin concerns about respecting petitioning rights and not interfering with legislative and executive functions, as discussed in the SAC Order at 20:9-15. Under such circumstances, an even more stringent standard than that applied here may be appropriate.

[4] Amphastar will not be heard to contradict its own representations at the hearing; therefore, these statements may be considered undisputed material facts on the record that are appropriate for judicial notice on this Rule 12(b)(6) motion. *In re Am. Continental/Lincoln Sav. & Loan Sec. Litig.*, 102 F.3d 1524, 1537 (9th Cir. 1996) (citing *Shaw v. Hahn*, 56 F.3d 1128, 1129 n.1 (9th Cir. 1995)), *rev'd on other grounds sub nom. Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998).

Finally, Amphastar's April 17 status report confirms that FDA concerns unrelated to Aventis' conduct continue to cause Amphastar's nonapproval.[5]

Thus, the TAC and Amphastar's own representations undercut the TAC's theory that Aventis caused Amphastar's market exclusion. Therefore, the SAC Order's conclusion that Amphastar does not plead causation and antitrust injury applies equally to the TAC. SAC Order at 29:12-18.

C. Prudential ripeness.

But even if the SAC did meet the causation and antitrust injury requirements, the SAC should still be dismissed for lack of prudential ripeness. *Alaska Right to Life Pol. Action Comm. v. Feldman*, 504 F.3d 840, 849 (9th Cir. 2007) ("Prudential ripeness . . . involves two overarching considerations: the fitness for judicial review and the hardship to the parties of withholding court consideration.") (internal quotations and citation omitted).

The following discussion therefore assumes that the TAC satisfies the intent-and-preparedness test—including that cognizable wrongful conduct by Aventis' has been at least a material cause of Amphastar's inability to come to market—as discussed in the SAC Order at 26:9-22, 28:20-29:11.

Fitness for judicial review. First, the above-mentioned concerns about respecting administrative proceedings strongly counsel against prudential ripeness before the FDA takes final action.

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[5] Amphastar filed the report under seal. The Court takes notice that the FDA's website publicly discloses more materials than Amphastar included in its purportedly confidential status report. That report refers to and summarizes a warning letter sent to one of Amphastar's suppliers but does not attach the letter. The full letter is available to the public, but Amphastar did not send it to the Court. FDA, Warning Letter to Shanghai No. 1 Biochem. & Pharm. Co. Ltd., http://www.fda.gov/foi/warning_letters/s7160c.htm (mentioning Amphastar by name).

Hardship to the parties. Second, the FDA could yet decline to approve Amphastar's application for reasons wholly unrelated to Aventis' conduct. The FDA could, at any time, raise additional concerns unrelated to those Aventis discusses in its citizen petition-related filings, thereby causing nonapproval or further approval delay. Amphastar represents that the FDA has done this before. Hearing Tr. at 7:10-18. Thus, causation on some potential damages—such as the total damages flowing from Amphastar's inability to enter the market—would still be speculative.[6] This would threaten grave prejudice to Aventis.[7]

D. State claims.

Amphastar's related state claims are also dismissed. Amphastar admitted at the hearing that its non-Sherman Act claims "rise and fall with the [federal] antitrust claims." Hearing Tr. at 25:25-26:1. Even if Amphastar were incorrect, the Court would decline to exercise its supplemental jurisdiction over the remaining state law claims. *Carlsbad Tech., Inc. v. HIF Bio., Inc.*, 566 U.S. ___, slip op. at 4-5 (May 4, 2009).

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[6] Citizen petition-defense and litigation-related damages may well be easier to determine, though Amphastar has already received an attorney fee award for the patent litigation.

[7] And even if the case proceeded only on a theory without potentially speculative market exclusion damages, Amphastar might later receive FDA approval. After approval, Amphastar would most likely seek to recalculate its damages to recover market exclusion damages. Neither additional damages proceedings nor premature litigation would be an efficient use of the resources of the Court and the parties.

III.

CONCLUSION

The May 19, 2009 hearing in this matter is taken OFF CALENDAR.

The TAC is DISMISSED WITHOUT PREJUDICE because it is still possible that the FDA could take action to obviate the causation and *Noerr-Pennington* issues. *See, e.g.*, *Louisiana Wholesale*, 2008 WL 169362, at *5, 2008 U.S. Dist. LEXIS 3611, at *13-17 (S.D.N.Y. Jan. 18, 2008) (discussing an FDA citizen petition disposition wherein the FDA expressly stated why the petition was "unfounded" and allowing an antitrust claim to proceed for that reason).

Amendment at this time would be futile. This case has been litigated for six years. Amphastar has, throughout the litigation, made assurances to this Court that the issues discussed in this Order would soon be resolved. The FDA still has not approved Amphastar's ANDA—nor taken any other final action. The Court concludes that some form of final action by the FDA is necessary to fairly adjudicate Amphastar's claims. Neither the parties nor the Court can predict what the FDA might do. The Court will not continue to wait; nor will it entertain further speculation by Amphastar about what another branch of government may do. Amphastar is DENIED further leave to amend. *See Allen v. City of Beverly Hills*, 911 F.2d 367, 373-74 (9th Cir. 1990).

IT IS SO ORDERED.

DATED: May 15, 2009

Mariana R. Pfaelzer

Hon. Mariana R. Pfaelzer
United States District Judge