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March 15, 2007

The Honorable Mary Pat Thynge
United States District Court
for the District of Delaware
844 North King Street
Wilmington, DE 19801

VIA E-FILING

Re: *Purdue Pharma L.P., et al. v. KV Pharmaceutical Company, et al.*
C.A. No. 07-032 (***)

Purdue Pharma L.P., et al. v. KV Pharmaceutical Company
C.A. No. 07-077 (***)

Dear Magistrate Judge Thynge:

I am writing on behalf of plaintiffs (collectively "Purdue") in the above-captioned cases to ask the Court to postpone the initial scheduling conference, which the Court has set for March 22, 2007, to allow Purdue to file a motion with the Judicial Panel on Multidistrict Litigation ("MDL Panel") pursuant to 28 U.S.C. § 1407 to coordinate and consolidate these actions with other actions relating to the same patents now pending and part of existing MDL proceedings in the Southern District of New York before the Hon. Sidney H. Stein.[1]

Purdue has conferred with each of the defendants. KV Pharmaceutical Company ("KV") agrees that the case should be transferred to MDL proceedings and that the scheduling conference should be postponed. Actavis Totowa ("Actavis") does not consent to either proposal.

Background

Purdue is the owner of three U.S. patents covering controlled-release formulations of oxycodone, an analgesic used to treat moderate to severe pain, such as pain associated with cancer, and methods of using those compositions. Purdue makes and sells OxyContin® Tablets

[1] The MDL litigation pending in the Southern District of New York is *In re OxyContin Antitrust Litigation,* 04-md-1603 (SHS).

("OxyContin®"), a product covered by these patents. Defendants have sought approval from the Food and Drug Administration ("FDA") to make and sell generic versions of OxyContin®. Defendants' answers include counterclaims for declaratory judgment of invalidity and unenforceability, and KV's answer includes a counterclaim for noninfringement (whereas Actavis admits that the use of its generic product will infringe the only patent asserted against it).

There are five similar patent cases currently pending before Judge Stein in New York, four of which have been consolidated in the MDL action there and the fifth is yet to be consolidated but has been designated as related.[2]

In this Court, each defendant's answer includes a "Walker Process" antitrust counterclaim, alleging that Purdue has violated the antitrust laws by obtaining its patents by deliberate fraud on the U.S. Patent and Trademark Office ("PTO") and asserting those patents in litigation. These antitrust counterclaims are substantially similar to sixty-nine (69) antitrust claims now pending before Judge Stein in the MDL.

Purdue respectfully submits that this Court should defer entry of a scheduling order to permit Purdue to file its motion to have these cases included as part of MDL proceedings.

The Court Has Authority To Defer Entry Of A Scheduling Order.

A request to stay proceedings pending a decision of the MDL Panel is addressed to the discretion of this Court. *See* MDL Panel Rule of Procedure 1.5 (filing of a motion to transfer an action before the MDL Panel "does not in any way limit the pretrial jurisdiction" of the district court in which that action is pending); *Landis v. North Am. Co.*, 299 U.S. 248, 254 (1936) (courts have inherent power to control their dockets in the interest of judicial economy). There are numerous decisions in which courts have granted stays pending a decision of the MDL Panel.[3]

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[2] These cases are: *Purdue Pharma L.P. et al. v. Impax Labs., Inc.*, No. 02-CIV-2803, 02-CIV-7569, 02-CIV-8036 (SHS); *Purdue Pharma L.P. et al. v. Boehringer Ingelheim GmbH et al.*, No. 99-CIV-3658 (SHS); *Rite Aid Corp. v. Purdue Pharma L.P. et al.*, No. 06-CV-15304 (SHS); *Safeway Inc. v. Purdue Pharma L.P. et al.*, No. 06-CV-15326 (SHS); and *Purdue Pharma L.P. et al. v. Mallinckrodt Inc.*, No. 06-CIV-13095 (SHS).

[3] *Azar v. Merck & Co.*, No. 06-cv-0579 (AS), 2006 U.S. Dist. LEXIS 78655, at *5 (N.D. Ind. Oct. 27, 2006); *Cintas Corp. v. Anderson*, No. 06CV262, 2006 U.S. Dist. LEXIS 40257, at *3 (D. Neb. June 15, 2006); *Floyd v. Merck & Co.*, No. 05-1332-T/An, 2005 U.S. Dist. LEXIS 28771, at *5 (W.D. Tenn. Nov. 8, 2005); *Strong v. Merck & Co.*, No. C 04-5062 MHP, 2005 U.S. Dist. LEXIS 2413, at *16-17 (N.D. Cal. Feb. 17, 2005); *Moore v. Wyeth-Ayerst Labs.*, 236 F. Supp. 2d 509, 513 (D. Md. 2002); *Falgoust v. Microsoft Corp.*, No. 00-0779, 2000 U.S. Dist. LEXIS 5417, at *8 (E.D. La. Apr. 19, 2000); *Aikins v. Microsoft Corp.*, No. 00-0242, 2000 U.S. Dist. LEXIS 4371, at *5 (E.D. La. Mar. 23, 2000); *Rivers v. Walt Disney Co.*, 980 F. Supp. 1358,

In *Rivers v. Walt Disney Co.*, 980 F. Supp. 1358 (C.D. Cal. 1997), the Central District of California granted a stay pending a decision by the MDL Panel regarding consolidation with four other cases filed in the Middle District of Florida. The court considered three factors in its analysis: "(1) potential prejudice to the non-moving party; (2) hardship and inequity to the moving party if the action [were] not stayed; and (3) the judicial resources that would be saved by avoiding duplicative litigation if the cases [were] in fact consolidated." *Id.* at 1360. Because neither party presented evidence of prejudice, the court focused on the third factor, judicial economy. The court determined that, absent a stay, it would spend resources and effort that would likely be duplicated by the judge presiding over the consolidated case. *Id.* at 1360-61. The court also found that stays pending an MDL decision were generally appropriate and furthered judicial economy unless there were basic jurisdictional issues such as venue to be resolved. *Id.* at 1361-62. In the present case, no such issues exist, and deferral of the entry of a scheduling order would likely conserve judicial resources.

The Court Should Defer Entry Of A Scheduling Order

Purdue's reasons for asking the Court to defer entry of a scheduling order are as follows:

1. **The MDL Panel is likely to grant Purdue's request.** There is substantial overlap between the claims pending in this Court and those pending in the MDL. The patents are the same, and the invalidity and unenforceability defenses (to the extent Purdue understands them from papers already filed) are substantially the same. And the antitrust issues raised here are substantially the same as the antitrust issues raised in the MDL proceedings as well.

Transfer of these actions to Multidistrict Litigation in New York will not prejudice the parties to the New York actions. The active patent cases now pending before Judge Stein are all in their early stages. No discovery has been taken, nor has a discovery schedule been set in *Mallinckrodt*, filed in November 2006, or in the declaratory judgment actions against Purdue brought in December 2006 by Rite Aid and Safeway (indeed, Mallinckrodt has not yet even filed its Answer). In *Impax* and *Boehringer*, the Court has ordered briefing on the issue of unenforceability, based on the trial record from an earlier litigation between Purdue and Endo Pharmaceuticals. If Judge Stein finds Purdue's patents enforceable on that record, Purdue and Impax would be at the beginning of litigation on the issues of infringement and patent validity. No schedule has been set for those proceedings. The *Boehringer* action is otherwise inactive, because the defendants have dropped their plans to make and sell an infringing product. The antitrust claims and counterclaims are all stayed pending resolution of the patent issues.

Judge Stein has considered the validity and infringement of these patents twice, in a 1999 preliminary injunction motion in *Boehringer* and in a 2003 bench trial in *Endo*. Because

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1362 (C.D. Cal. 1997); *Rosenfeld v. Hartford Fire Ins. Co.*, No. 88 Civ. 2153 (MJL), 1988 U.S. Dist. LEXIS 4068, at *5 (S.D.N.Y. May 10, 1988).

of his familiarity with the issues, conservation of judicial resources suggests that his Court would be the logical place for the two actions now pending before this Court to be transferred.

2. **Deferring the entry of a scheduling order in this Court at this time will not prejudice the defendants.** As discussed *supra* p. 1, KV agrees that this action should be transferred to a multi-district litigation and that the scheduling teleconference should be deferred. Actavis does not agree to either proposal. Notwithstanding Actavis' position, there will be no prejudice to either defendant from proceeding as Purdue proposes.

Purdue plans to file its motion before the MDL Panel promptly, within two weeks. It is Purdue's intention to move these cases forward expeditiously.[4]

Neither defendant has received FDA approval for its proposed generic product. By statute, the commencement of Purdue's suits resulted in a 30-month stay of FDA approval to allow the courts to determine the contested issues of validity and infringement. 21 U.S.C. § 355(j)(5)(B)(iii). Because the Purdue documents relevant to the disputed issues have been collected and processed for production in earlier litigations, Purdue believes that any time lost while waiting for the MDL Panel to decide how to proceed will be offset by other efficiencies once these litigations move into active discovery. Assuming that defendants cooperate in providing discovery, there is every reason to believe that the patent aspects of these actions will be concluded within the 30-month statutory stay.

3. **Purdue would be prejudiced by the entry of a scheduling order when no such order has been entered in the parallel New York cases.** As discussed above, active discovery is not currently underway in the New York actions. Waiting to begin active discovery in the two actions before this Court will increase the likelihood that Purdue will only have to produce documents once, to make its witnesses available for deposition once, and to conduct pretrial activities in these cases once. Defendants will also benefit from a coordinated proceeding in their discovery of Purdue for the same reasons.

4. **Deferring the entry of a scheduling order will best conserve the resources of the Court.** Similarly, deferring entry of a scheduling order will benefit both this Court and Judge Stein in the MDL proceeding. Discovery disputes, if any, will be raised and resolved once. Pretrial proceedings can be coordinated to minimize the risk of inconsistent rulings.

If the MDL Panel grants Purdue's motion, this Court will have "needlessly expended its energies familiarizing itself with the intricacies of a case that would be heard by another judge." *Rivers*, 980 F. Supp. at 1360. Moreover, any efforts by this Court at case management would have to be repeated by Judge Stein. *See id.* at 1361.

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[4] Purdue is considering whether there are sufficient facts to bring a motion to transfer these actions to New York for all purposes under 28 U.S.C. § 1404(a). Absent agreement from the defendants to a transfer, Purdue will seek to develop these facts in the early stages of discovery.

For these reasons, Purdue respectfully requests that the Court postpone the scheduling teleconference set for March 22, and defer entry of a scheduling order at this time.

Respectfully,

Jack B. Blumenfeld (I.D. No. 1014)

JBB/dlb

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