IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

ANACOR PHARMACEUTICALS, INC., Plaintiff, v. MYLAN PHARMACEUTICALS INC. and MYLAN INC., Defendants.	Civil Action No. 1:18-cv-00202-IMK

MEMORANDUM IN SUPPORT OF THE MYLAN DEFENDANTS' RESPONSE TO ANACOR'S MOTION TO STAY CASE

I. INTRODUCTION

Defendants Mylan Pharmaceuticals Inc. ("MPI") and Mylan Inc., (collectively, "the Mylan Defendants") herein respectfully respond to Anacor Pharmaceuticals, Inc.'s ("Anacor") Motion to Stay (Dkt. No. 25).

The Mylan Defendants are ready and able to immediately proceed with the present litigation. However, in the interest of compromise and preservation of judicial resources, the Mylan Defendants are amenable to a brief stay of the litigation until the Patent Trial and Appeal Board ("PTAB") issues Final Written Decisions in the ongoing *inter partes* reviews ("IPR") of the four patents-in-suit so long as such a stay does not result in an extension of the regulatory stay of approval of MPI's accused ANDA product or delay resolution of the Mylan Defendants' Fed. R. Civ. P. 12 motion in the parallel litigation pending in the District of Delaware. The Mylan Defendants understand that Anacor is amendable to these conditions, and that the parties disagree only with respect to when the stay of this litigation should end.

Specifically, in an attempt to leverage a competitive advantage from a stay of this litigation, Anacor requests that (1) if the Final Written Decision finds some claim(s) patentable, the stay lift, allowing litigation of those claims, and (2) if the Final Written Decision finds all claims unpatentable, the stay remain in place (preserving the stay of FDA approval of MPI's ANDA product, and thus postponing generic competition for Anacor's brand product) while Anacor seeks an appeal. This is not acceptable, and would impose a severe prejudice on the Mylan Defendants and grant Anacor an unjustified competitive advantage.

Finally, staying this matter while the JPML decides Anacor's motion to transfer this matter to Delaware is unwarranted. The Mylan Defendants intend to oppose Anacor's request that the JPML transfer this case to pending parallel litigation that Anacor filed against the Mylan

Defendants in the a forum where venue is improper, and likewise oppose delaying this litigation in view of that transparent attempt at forum shopping.

As a practical matter, this Court should stay this matter until the Final Written Decisions are issued in the IPRs of the patents-in-suit. At that time, the Court and the parties can address the appropriate manner in which to proceed.

II. BACKGROUND

A. Northern District of West Virginia and District of Delaware Litigations

This action is one of two nearly identical matters arising out of MPI's filing of an ANDA with FDA seeking approval for a tavaborole topical solution, 5%. Dkt. No. 1 at ¶ 1; *Anacor Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, Case No. 18-cv-1699-RGA (D. Del.). Anacor filed suit against the Mylan Defendants in the District of Delaware on October 29, 2018[1] and in the present Court on October 30, 2018. Anacor filed nearly identical patent infringement suits against fourteen defendant groups, each alleging that the filing of an ANDA infringed U.S. Patent Nos. 9,549,938; 9,566,289; 9,566,290; and 9,572,823 ("patents-in-suit"). Notably, in the District of Delaware, while Anacor combined its claims against the other thirteen defendants in only two complaints, Anacor filed a separate complaint against MPI and Mylan Inc., likely anticipating a venue objection and challenge. On December 21, 2018, in the District of Delaware action, the Mylan Defendants filed a Motion to Dismiss for Improper Venue and Failure to State a Claim detailing why venue is improper in that district for both MPI and Mylan Inc., and why Mylan Inc. (which did not file the accused ANDA) is not a proper party to the litigation. Briefing is not yet complete on that motion. No Fed. R. Civ. Pro. 16 conference is scheduled in the District of Delaware matter.

[1] Anacor's complaint was filed in the District of Delaware nearly two weeks after that court found that venue was not proper with respect to MPI in that district. *Bristol-Myers Squibb Co. v. Mylan Pham.*, No. 17-374, 2018 WL 5109836, at *5 (D. Del. Oct. 18, 2018).

In the present case, the Mylan Defendants filed their Answer and Counterclaims on December 14, 2018, and Anacor filed its Answer to those Counterclaims on January 4, 2019. A Fed. R. Civ. P. 16 scheduling conference is set for March 28, 2019. On January 17, 2019, Anacor moved to continue that conference and related deadlines until resolution of the present motion. Dkt. No. 37. Finding no good cause for the requested continuance, the Court denied that motion on January 18, 2019. Dkt. No. 38.

B. IPRs of the Patents-In-Suit

The four patents-in-suit are presently the subject of IPRs. Those IPRs have been pending since November 2017, and oral argument is scheduled to occur on March 1, 2019. Final Written Decisions are due to issue no later than June 8, 2019 (U.S. Patent Nos. 9,549,938 and 9,566,289) and June 14, 2019 (U.S. Patent Nos. 9,566,290 and 9,572,823). MPI is a co-petitioner in all four IPRs.

III. LEGAL STANDARDS

It is within the court's discretion to grant or deny a request to stay litigation pending IPR. *454 Life Scis. Corp. v. Ion Torrent Sys., Inc.*, Case No. 15-595-LPS, 2016 WL 6594083, at *2 (D. Del. Nov. 7, 2016); *Alcon Labs., Inc. v. Akorn, Inc.*, Case No. 15-285-RMB, 2016 WL 99201, at *1 (D.N.J. Jan. 8, 2016) ("[S]taying a patent case in which an IPR request has been granted is within the discretion of the Court."). "Typically, courts consider three factors in deciding how to exercise this discretion: (1) whether a stay will simplify the issues for trial; (2) the status of the litigation, particularly whether discovery is complete and a trial date has been set; and (3) whether a stay would cause the non-movant to suffer undue prejudice from any delay or allow the movant to gain a clear tactical advantage." *454 Life Scis. Corp.*, 2016 WL 6594083, at *2.

IV. ARGUMENT

A. Any Stay of This Litigation Should Expire Upon Issuance of the IPR Final Written Decisions

In the interest of judicial economy and compromise, the Mylan Defendants are amenable to staying this litigation until issuance of the PTAB's IPR Final Written Decisions so long as the stay: (i) expires upon issuance of the IPR Final Written Decisions, (ii) does not serve as a basis for extension of the regulatory stay of approval of MPI's ANDA product; and (iii) does not delay resolution of the Mylan Defendants' Fed. R. Civ. P. 12 motion pending in the District of Delaware.[2] The Mylan Defendants understand that Anacor has agreed to the latter two conditions, leaving in dispute only the timing of the expiration of Anacor's requested stay.

Any stay of this litigation should expire upon issuance of the IPR Final Written Decisions. ***First***, regardless of the outcome of the IPRs, the Mylan Defendants should be permitted to litigate all available defenses in the District Court in a timely manner, including, *inter alia*, non-infringement and non-prior art based invalidity.

Second, Anacor's request that the stay remain in place pending appeal should the IPRs result in a finding that all of the claims of the patents-in-suit are unpatentable is unjustifiably prejudicial to the Mylan Defendants. Anacor initiated this litigation, triggering a regulatory stay of approval of MPI's ANDA. In order to terminate that regulatory stay of approval, MPI must obtain a court order—a Final Written Decision from the PTAB will not suffice. 21 C.F.R. § 314.107(b)(3).[3] Maintaining a stay of the litigation through appeal would severely prejudice

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[2] The Mylan Defendants agree that the IPR Final Written Decisions have the potential to simplify the issues to be litigated, and that the present litigation, which is in the very early stages, has not proceeded to an extent that would warrant denial of a stay pending issuance of the IPR Final Written Decisions.

[3] The decision cited by Anacor, *Novartis AG v. Noven Pharma. Inc.*, 853 F.3d 1289, 1294 (Fed. Cir. 2017) is inapplicable to the present facts. Dkt. No. 26 at 8. In *Novartis*, the Federal Circuit noted that the PTAB's findings that patent claims would have been obvious in view of prior art

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