

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

ANACOR PHARMACEUTICALS, INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 18-202-IMK
)	
MYLAN PHARMACEUTICALS INC., and)	
MYLAN INC.,)	
)	
Defendants.)	
)	

JOINT REPORT OF RULE 26(f) MEETING AND PROPOSED DISCOVERY PLAN

Pursuant to Federal Rules of Civil Procedure 16 and 26(f), Local Civil Rules 16.01(b) and (c), and the Court’s December 4, 2018 Order (D.I. 20), the parties, by and through their undersigned counsel, jointly submit this Report and Proposed Discovery Plan. Counsel for the parties participated in a telephone conference pursuant to Order, and as required by Rule 26(f), on January 17, 2019 to discuss a proposal for proceeding, and the parties exchanged various email communications as to the planning report and an exchange of proposals. The participants in the initial conference were:

- James F. Companion on behalf of Plaintiff Anacor Pharmaceuticals, Inc. (“Anacor”);
and
- William J. O’Brien on behalf of Mylan Pharmaceuticals Inc. (“MPI”) and Mylan Inc. (collectively, “the Mylan Defendants”).

The parties discussed matters under Federal Rules 16 and 26(f) and Local Rule 16.01(b).

I. CASE BACKGROUND

A. Overview

This is a Hatch-Waxman action arising out of MPI's filing of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Anacor's Kerydin[®] (TAVABOROLE) TOPICAL SOLUTION, 5% ("Kerydin"), prior to the expiration of U.S. Patent Nos. 9,459,938; 9,566,289; 9,566,290; and 9,572,823 (collectively, "the patents-in-suit"). MPI's ANDA is one of fourteen ANDAs that have been filed with regard to Kerydin.

Anacor sued all fourteen ANDA filers—including the Mylan Defendants—in the United States District Court for the Delaware in October 2018.¹ Anacor also filed a fourth, substantively identical lawsuit against the Mylan Defendants in this district (the present action). The Mylan Defendants filed a Motion to Dismiss the Delaware action. *Anacor Pharm., Inc. v. Mylan Pharm. Inc. & Mylan Inc.*, No. 1:18-cv-01699-RGA (D. Del.), D.I. 14. Anacor voluntarily dismissed the action against the Mylan Defendants in Delaware on March 1, 2019. *See Anacor Pharm., Inc. v. Mylan Pharm. Inc. & Mylan Inc.*, No. 1:18-cv-01699-RGA (D. Del.), D.I. 28. The remaining Delaware cases (against all ANDA filers other than the Mylan Defendants) are currently before Judge Richard G. Andrews and are at an early procedural stage: most defendants have responded to Anacor's complaints, but no conferences have been scheduled or held, no discovery has taken place, and no schedules have been set.

¹ The Delaware actions are captioned as follows: *Anacor Pharm., Inc. v. Lupin Ltd., Lupin Pharm., Inc., Encube Ethicals Pvt. Ltd., Glasshouse Pharm. Ltd. Canada, & FlatWing Pharma, LLC*, No. 1:18-cv-001606-RGA (D. Del.); *Anacor Pharm., Inc. v. Ascent Pharm., Inc., Zydus Pharm. (USA) Inc., Cadila Healthcare Ltd., Apotex Inc., Apotex Corp., Amneal Pharm. LLC, Perrigo Pharma Int'l DAC, Perrigo Co. plc, Aleor Dermaceuticals Ltd., Cipla Ltd., Cipla USA, Inc., Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., Taro Pharm. U.S.A., Inc., & Taro Pharm. Indus., Ltd.*, No. 1:18-cv-001673-RGA (D. Del.); and *Anacor Pharm., Inc. v. Mylan Pharm. Inc. & Mylan Inc.*, No. 1:18-cv-01699-RGA (D. Del.).

B. The *Inter Partes* Review Petitions

Separately, in November 2017, FlatWing Pharmaceuticals, LLC (“FlatWing”) petitioned the Patent Trial and Appeal Board (“PTAB”) for *inter partes* review (“IPR”) of all of the claims of the patents-in-suit. In July 2018, MPI filed similar petitions with the PTAB seeking to invalidate the same patents. The PTAB has instituted trial on all of FlatWing’s and MPI’s petitions and has consolidated them into the following four IPRs: IPR No. 2018-00168; IPR No. 2018-00169; IPR No. 2018-00170; and IPR No. 2018-00171. The PTAB heard oral argument on March 1, 2019. Anacor and MPI anticipate that the PTAB will issue its final written decisions in June 2019.

C. Motion to Transfer

On January 7, 2019, Anacor filed a motion with the Judicial Panel on Multidistrict Litigation (“JPML”) seeking to transfer the present action to Judge Andrews in the District of Delaware for coordinated and consolidated pretrial proceedings with the cases already pending in that district. *See In re: Kerydin (Tavaborole Topical Solution 5% Patent Litig.*, MDL No. 2884, D.I. 1 (J.P.M.L. Jan. 7, 2019). Anacor’s transfer motion is fully briefed and is scheduled for oral argument on March 28, 2019.

D. Motions to Stay

On November 26, 2018, FlatWing moved to stay the Delaware case in which it is a defendant until the PTAB issues a final written decision in the pending IPRs. In response, on December 10, 2018, Anacor filed a cross-motion to stay all three Delaware cases. The Delaware court denied both motions in an oral order on March 1, 2019. *See Anacor Pharm., Inc. v. Lupin Ltd.*, No. 18-cv-1606-RGA, D.I. 55 (D. Del. Mar. 1, 2019); *Anacor Pharm., Inc. v. Ascent Pharm., Inc.*, No. 18-1673-RGA, D.I. 90 (D. Del. Mar. 1, 2019); *Anacor Pharm., Inc. v. Mylan Pharm. Inc.*, No. 18-1699-RGA, D.I. 27 (D. Del. Mar. 1, 2019).

In the present action, on January 14, 2019, Anacor moved to stay this case until the PTAB issues final written decisions in the pending IPRs, and if the PTAB finds that all of the claims of the patents are unpatentable, to continue the stay until the time for appeal of the PTAB's decisions has expired or any appeals have terminated. D.I. 25. In the alternative, Anacor moved for a stay until Anacor's motion to transfer has been decided by the JPML. *Id.* Anacor's stay motion remains pending.

II. DISCOVERY PLAN

The parties jointly propose the following discovery plan.

A. Initial Disclosures

Pursuant to the Court's December 4, 2018 Order (D.I. 20), the parties exchanged initial disclosures on February 22, 2019.

B. Subjects of Discovery, Completion of Discovery, and Whether Discovery Should Be Conducted in Phases

Discovery will be needed on the following subjects:

1. Infringement of the patents-in-suit.
2. Validity of the patents-in-suit, including objective indicia of nonobviousness.
3. Claims and/or defenses asserted in Anacor's Complaint (D.I. 1), the Mylan Defendants' Answer and Counterclaims (D.I. 21), and Anacor's Answer to the Mylan Defendants' Counterclaims (D.I. 23).

Anacor submits that it is premature to set a case schedule while Anacor's motion to stay and motion to transfer are pending before this Court and the JPML. The Mylan Defendants submit that preparing a case schedule can do no harm and will be more efficient if the Court denies Anacor's Motion to Stay. If the Court prefers to set a schedule now, the parties' respective proposals, including proposed dates for the completion of discovery and fact and expert discovery phases, are set forth in attached Exhibit A.

C. Issues about Disclosure, Discovery, and Preservation of Electronically Stored Information

The parties will negotiate an appropriate Protective Order for submission to the Court. Pending entry of a protective order, discovery and disclosures deemed confidential by a party shall be produced to the adverse party on an “Outside Counsel Eyes Only” basis.

The parties anticipate exchanging electronically stored information (“ESI”), and will jointly prepare for this Court’s consideration a proposed stipulated ESI agreement addressing the form or forms in which ESI should be produced.

D. Limitations on Discovery

The parties agree that discovery should be conducted in accordance with the Federal Rules of Civil Procedure and the Local Rules of this Court. The parties agree to be reasonable and cooperative with respect to the number and timing of document requests and requests for admissions as further clarified below.

1. Informal Coordination

The parties agree that, in the event the JPML declines to transfer this matter to the District of Delaware for coordinated pretrial proceedings, this matter should be informally coordinated with the Delaware actions so as to minimize the burden and expense of discovery on the parties and the Court. If Anacor’s motion to transfer is denied, the parties will confer and make a joint proposal to the Court regarding appropriate informal coordination.

2. Written and Document Discovery

a. Interrogatories

Anacor shall be entitled to serve a maximum of fifteen (15) interrogatories, including contention interrogatories and sub-parts, on Defendants. Defendants collectively shall be

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