BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re Kerydin Patent Litigation	MDL No. _____

MOTION OF PLAINTIFF FOR TRANSFER OF ACTION TO THE DISTRICT OF DELAWARE PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATED AND CONSOLIDATED PRETRIAL PROCEEDINGS

NOW COMES Anacor Pharmaceuticals, Inc. ("Anacor" or "Plaintiff"), plaintiff in:

- *Anacor Pharmaceuticals, Inc. v. Lupin Limited, Lupin Pharmaceuticals, Inc., Encube Ethicals Pvt. Ltd., Glasshouse Pharmaceuticals Limited Canada, FlatWing Pharmaceuticals, LLC,* Case No. 1:18-cv-001606-RGA (D. Del.);
- *Anacor Pharmaceuticals, Inc. v. Ascent Pharmaceuticals, Inc., Zydus Pharmaceuticals (USA) Inc., Cadila Healthcare Ltd., Apotex Inc., Apotex Corp., Amneal Pharmaceuticals LLC, Perrigo Pharma International DAC, Perrigo Company plc, Aleor Dermaceuticals Limited, Cipla Limited, Cipla USA, Inc., Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc., Taro Pharmaceuticals U.S.A., Inc. Taro Pharmaceutical Industries, Ltd.*, Case No. 1:18-cv-001673-RGA (D. Del.);
- *Anacor Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc., Mylan Inc.*, Case No. 1:18-cv-01699-RGA (D. Del.); and
- *Anacor Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc., Mylan Inc.*, Case No. 1:18-cv-00202-IMK (N.D. W. Va.).

Anacor moves the Judicial Panel on Multidistrict Litigation, by and through its undersigned counsel, to enter an order pursuant to 28 U.S.C. § 1407 and Rule 6.2 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, transferring *Anacor Pharmaceuticals, Inc. v. Mylan Pharmaceuticals, Inc., Mylan Inc.*, Case No. 1:18-cv-00202-IMK, pending in the Northern District of West Virginia, to Judge Richard G. Andrews in the United States District Court for the District of Delaware, for coordinated and consolidated pretrial proceedings with three cases already pending in that district.

Transfer for pretrial consolidation and coordination is proper and necessary for the following reasons, as more fully explained in the accompanying memorandum:

1. This motion seeks transfer and consolidation of four actions for patent infringement brought under the patent laws of the United States, Title 35, United States Code, by Plaintiff Anacor against the following defendants: Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"); Encube Ethicals Pvt. Ltd. ("Encube"); Glasshouse Pharmaceuticals Limited Canada ("Glasshouse"); FlatWing Pharmaceuticals, LLC ("FlatWing"); Ascent Pharmaceuticals, Inc. ("Ascent"); Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (collectively, "Zydus"); Apotex Inc. and Apotex Corp. (collectively, "Apotex"); Amneal Pharmaceuticals LLC ("Amneal"); Perrigo Pharma International DAC and Perrigo Company plc (collectively, "Perrigo"); Aleor Dermaceuticals Limited ("Aleor"); Cipla Limited and Cipla USA, Inc. (collectively, "Cipla"); Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. (collectively, "Aurobindo"); Taro Pharmaceuticals U.S.A., Inc. and Taro Pharmaceutical Industries, Ltd. (collectively, "Taro"); and Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively "Mylan") in the United States District Courts for the District of Delaware and the Northern District of West Virginia. The defendants listed above are collectively referred to herein as "Defendants."

2. All four actions arise out of Defendants' filing of Abbreviated New Drug Applications ("ANDAs") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Kerydin® (TAVABOROLE) TOPICAL SOLUTION 5% ("Kerydin") prior to the expiration of U.S. Patent No. 9,459,938 ("the '938 patent"), U.S. Patent No. 9,566,289 ("the '289 patent"), U.S. Patent No. 9,566,290 ("the '290 patent"), and U.S. Patent No. 9,572,823 ("the '823 patent") (collectively, "the patents-in-suit").

3. Each of the patents-in-suit is listed in the FDA's Orange Book for Kerydin.

4. Anacor filed each of the above-listed actions in response to separate letters received from Lupin, Encube, Glasshouse, FlatWing, Ascent, Zydus, Apotex, Amneal, Perrigo, Aleor, Cipla, Aurobindo, Taro, and Mylan in September 2018 notifying Anacor that each of those parties had submitted an ANDA to the FDA (these fourteen ANDAs are collectively referred to as "Defendants' ANDAs").

5. The notice letters informed Anacor that Defendants submitted their ANDAs to the FDA in order to obtain approval under the Federal Food, Drug & Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, sale and/or importation of generic versions of Kerydin prior to the expiration of the patents-in-suit.

6. The notice letters informed Anacor that Defendants' ANDAs were submitted with certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that each of the patents-in-suit is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of the products that are the subject of Defendants' ANDAs ("Defendants' ANDA Products").

7. Anacor filed each of the above-listed actions in October 2018.

8. In the above-listed actions, Anacor alleges, among other things, that the submission of Defendants' ANDAs before the expiration of the patents-in-suit constituted acts of infringement of those patents under 35 U.S.C. § 271(e)(2)(A).

9. All of the above-listed actions therefore involve the same core issue: whether Defendants have infringed any valid and enforceable claims of the patents-in-suit.

10. The above-listed actions present numerous common issues of fact and law, including without limitation the technology underlying the patents-in-suit; the prosecution

history of the patents-in-suit; claim construction; the scope and content of the prior art; and secondary indicia of non-obviousness, such as the commercial success of any products embodying the patents-in-suit and any long-felt but unmet need for the inventions described therein.

11. All of the above-listed actions are in their earliest stages. As of the date of filing of this motion, no conferences have been held with any of the courts; no discovery has taken place; and no substantive orders have been issued.

12. On November 26, 2018, FlatWing moved to stay civil action No. 1:18-cv-001606-RGA, pending in the District of Delaware, until the Patent Trial and Appeal Board ("PTAB") enters a final written decision in one of four *inter partes* review proceedings that are currently pending in that forum.

13. In the aforementioned *inter partes* review proceedings, FlatWing and Mylan are challenging the validity of the patents-in-suit.

14. In response to FlatWing's motion to stay, on December 10, 2018, Anacor cross-moved to stay all three civil actions it filed in the District of Delaware (C.A. No. 1:18-cv-001606-RGA, C.A. No. 1:18-cv-001673-RGA, and 1:18-cv-01699-RGA) until the PTAB enters a final written decision in the four *inter partes* review proceedings identified in FlatWing's motion, and, potentially, to continue the stay through any appeal of the PTAB's decision.

15. The parties are still in the process of briefing FlatWing's and Anacor's stay motions, which remain pending.

16. Anacor has not yet moved to stay the action against Mylan pending in West Virginia, C.A. No. 1:18-cv-00202-IMK, but anticipates that it will do so, and that it will propose the same stay terms it has proposed in the three Delaware actions.

17. On December 21, 2018, Mylan moved to dismiss Anacor's complaint against Mylan in Delaware in C.A. No. 1:18-cv-01699-RGA asserting improper venue under Federal Rule of Civil Procedure 12(b)(3) and failure to state a claim under Rule 12(b)(6).

18. Anacor and Mylan are currently discussing a schedule for venue discovery and briefing of Mylan's motion.

19. Transfer and consolidation of the above-listed actions is necessary to: (a) eliminate the potential for inconsistent rulings on pretrial motions, including but not limited to, FlatWing's and Anacor's motions to stay, Mylan's motion to dismiss for failure to state a claim, and any claim construction rulings; (b) eliminate the burden of duplicative discovery on common issues; (c) prevent inconsistent pretrial rulings; (d) avoid the unnecessary use of judicial resources; and (e) reduce the overall costs and burdens for all of the parties.

20. Moreover, because the above-listed actions assert infringement through the submission of ANDAs, the effect of having inconsistent rulings regarding FDA procedures, claim construction, validity, and ANDA-based infringement would be significant, deleterious, and an unnecessary strain on court resources.

21. Three of the above-listed actions are pending before Judge Andrews in the District of Delaware. All twenty-two Defendants, including Mylan Pharmaceuticals Inc. and Mylan Inc., are named defendants in one of those three Delaware actions.

22. In addition, Anacor has sued Mylan Pharmaceuticals Inc. and Mylan Inc. in a fourth action pending before Judge Keeley in the Northern District of West Virginia.

23. Nearly all of the parties have previously engaged in patent litigation in the District of Delaware and/or have consented to personal jurisdiction and venue in Delaware.

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