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

ANACOR PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	
v.	)	Civil Action No. 1:18-CV-202
MYLAN PHARMACEUTICALS INC., and MYLAN INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiff Anacor Pharmaceuticals, Inc. ("Anacor"), by its attorneys, for its Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code that arises out of Defendants' 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 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"). These four patents are referred to collectively herein as "the patents-in-suit."

2. Mylan Pharmaceuticals Inc. notified Anacor by letter dated September 17, 2018 ("Mylan's Notice Letter") that it had submitted to the FDA ANDA No. 212065 ("Mylan's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use and/or

sale of a generic tavaborole topical solution ("Mylan's ANDA Product") prior to the expiration of the patents-in-suit.

3. Upon information and belief, Mylan's ANDA Product is a drug product that is a generic version of Kerydin, containing the same or equivalent ingredients in the same or equivalent amounts.

PARTIES

4. Plaintiff Anacor is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 235 East 42nd Street, New York, New York 10017.

5. Upon information and belief, defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505. Upon information and belief, Mylan Pharmaceuticals Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs for the U.S. market.

6. Upon information and belief, defendant Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having a principal place of business at 1500 Corporate Drive, Canonsburg, PA 15317. Upon information and belief, Mylan Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products through various operating subsidiaries, including Mylan Pharmaceuticals Inc.

7. Upon information and belief, Mylan Pharmaceuticals Inc. is a wholly owned subsidiary of Mylan Inc. Mylan Pharmaceuticals Inc. and Mylan Inc. are collectively referred to herein as "Mylan."

JURISDICTION

8. Jurisdiction is proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. This Court has personal jurisdiction over Mylan.

10. Mylan Pharmaceuticals Inc. is subject to personal jurisdiction in West Virginia because, among other things, it has purposely availed itself of the benefits and protections of West Virginia's laws such that it should reasonably anticipate being haled into court here. Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, is qualified to do business in West Virginia, and has appointed a registered agent for service of process in West Virginia. It therefore has consented to general jurisdiction in West Virginia. Upon information and belief, Mylan Pharmaceuticals Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of West Virginia and therefore transacts business within the State of West Virginia related to Anacor's claims, and/or has engaged in systematic and continuous business contacts within the State of West Virginia.

11. Mylan Inc. is subject to personal jurisdiction in West Virginia because, among other things, Mylan Inc., itself and through its wholly-owned subsidiary Mylan Pharmaceuticals Inc., has purposefully availed itself of the benefits and protections of West Virginia's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Mylan Inc., itself and through its subsidiary Mylan Pharmaceuticals Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of West Virginia and therefore transacts business within the State of West Virginia, and/or has engaged in systematic and continuous business contacts within

the State of West Virginia. In addition, Mylan Inc. is subject to personal jurisdiction in West Virginia because, upon information and belief, it controls and dominates Mylan Pharmaceuticals Inc. and therefore the activities of Mylan Pharmaceuticals Inc. in this jurisdiction are attributed to Mylan Inc.

12. Upon information and belief, if Mylan's ANDA is approved, Mylan will directly or indirectly manufacture, market, sell, and/or distribute Mylan's ANDA Product within the United States, including in West Virginia, consistently with Mylan's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Mylan regularly does business in West Virginia, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in West Virginia. Upon information and belief, Mylan's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in West Virginia. Upon information and belief, Mylan's ANDA Product will be prescribed by physicians practicing in West Virginia, dispensed by pharmacies located within West Virginia, and used by patients in West Virginia. Each of these activities would have a substantial effect within West Virginia and would constitute infringement of Anacor's patents in the event that Mylan's ANDA Product is approved before the patents expire.

13. Upon information and belief, Mylan derives substantial revenue from generic pharmaceutical products that are used and/or consumed within West Virginia, and which are manufactured by Mylan and/or for which Mylan Pharmaceuticals Inc. or Mylan Inc. is the named applicant on approved ANDAs. Upon information and belief, various products for which Mylan Pharmaceuticals Inc. or Mylan Inc. is the named applicant on approved ANDAs are available at retail pharmacies in West Virginia.

THE PATENTS-IN-SUIT

14. Anacor incorporates each of the preceding paragraphs 1–13 as if fully set forth herein.

15. The inventors named on each of the patents-in-suit are Stephen J. Baker, Tsutomu Akama, Vincent S. Hernandez, Karin M. Hold, Kirk Maples, Jacob J. Plattner, Virginia Sanders, Yong-Kang Zhang, Gregory T. Fieldson, and James J. Leyden (collectively, "the Named Inventors").

16. The '938 patent, entitled "Boron-Containing Small Molecules" (Exhibit A hereto), was duly and legally issued on January 24, 2017, to Anacor, as assignee of the Named Inventors.

17. The '938 patent claims, *inter alia*, a method of treating a *Tinea unguium* infection of a toenail of a human, the method comprising topically administering to the toenail of the human a pharmaceutical composition comprising 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole or a pharmaceutically acceptable salt thereof in an amount sufficient to treat the infection, wherein the pharmaceutical composition is in the form of a solution comprising 5% w/w 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole.

18. The '938 patent claims, *inter alia*, a method of treating a *Tinea unguium* infection of a toenail of a human, the method comprising topically administering to the toenail of the human a pharmaceutical composition comprising 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole or a pharmaceutically acceptable salt thereof in an amount sufficient to treat the infection, wherein the *Tinea unguium* infection is due to *Trichophyton rubrum* or *Trichophyton mentagrophytes*, and wherein the pharmaceutical composition is in the form of a solution comprising 5% w/w 1,3-dihydro-5-fluoro-1-hydroxy-2,1-benzoxaborole.

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