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

ANACOR PHARMACEUTICALS, INC.,	)	
	)	
	)	
Plaintiff,	)	
	)	C.A. No. 1:18-CV-00202-IMK
v.	)	
	)	
MYLAN PHARMACEUTICALS INC. and MYLAN INC.,	)	
	)	
	)	
Defendants.	)	

DEFENDANTS' ANSWER TO PLAINTIFF'S COMPLAINT AND COUNTERCLAIMS

Defendants Mylan Pharmaceuticals Inc. ("MPI") and Mylan, Inc., (collectively, "the Mylan Defendants"), by and through their counsel, hereby answer Plaintiff Anacor Pharmaceuticals, Inc.'s ("Anacor" or "Plaintiff") Complaint. The Mylan Defendants deny each and every allegation contained in Anacor's Complaint ("Complaint") that is not expressly admitted below. The Mylan Defendants answer each paragraph of Anacor's Complaint in the order set forth therein 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."

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer is required, the Mylan Defendants admit that MPI filed Abbreviated New Drug Application ("ANDA") No. 212065 with United States Food and Drug Administration ("FDA") seeking approval for its Tavaborole 5% topical solution product. The Mylan Defendants deny

that Mylan Inc. is a proper party to this action. To the extent there are allegations not expressly admitted above, such allegations are denied.

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.

ANSWER: The Mylan Defendants admit that MPI sent Anacor a notice letter dated September 17, 2018 pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA") stating that MPI had submitted ANDA No. 212065 to FDA. To the extent there are allegations not expressly admitted, such allegations are denied.

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.

ANSWER: The Mylan Defendants admit that the product that is the subject of ANDA No. 212065 ("MPI's ANDA Product") contains the active ingredient Tavaborole in 5% dosage strength intended for topical administration. The Mylan Defendants lack sufficient knowledge and information to form a belief as to the truth of the remaining allegations contained in paragraph 3 of the Complaint and, on that basis, deny them.

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.

ANSWER: The Mylan Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 4 of the Complaint and, on that basis, deny them.

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.

ANSWER: MPI admits that it is incorporated in West Virginia and has its principal place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505. MPI further admits that it is in the business of, among other things, manufacturing and selling generic medicines.

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.

ANSWER: Mylan Inc. admits that it is incorporated in Pennsylvania and has its principal place of business at 1000 Mylan Boulevard, Robert J. Coury Global Center, Canonsburg, Pennsylvania 15317. The Mylan Defendants deny that Mylan Inc. is a proper party to this action. To the extent there are allegations not expressly admitted above, such allegations are denied.

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."

ANSWER: The Mylan Defendants admit that MPI is wholly-owned by Mylan Inc. The Mylan Defendants deny that Mylan Inc. is a proper party to this action. To the extent there are allegations not expressly admitted above, such allegations are denied.

JURISDICTION

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

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is required, the Mylan Defendants deny that this Court has subject matter jurisdiction over allegations related to any alleged infringement under 35 U.S.C. §§ 271(a), (b),

(c), and/or (g). The Mylan Defendants deny that Mylan Inc. is a proper party to this action. To the extent there are allegations not expressly admitted above, such allegations are denied.

9. This Court has personal jurisdiction over Mylan.

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, for the purposes of this litigation, the Mylan Defendants do not contest personal jurisdiction in West Virginia.

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.

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, for the purposes of this litigation, the Mylan Defendants do not contest personal jurisdiction in West Virginia. To the extent there are allegations not expressly admitted above, such allegations are denied.

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.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, for the purposes of this litigation, the Mylan Defendants do not contest personal jurisdiction in West Virginia. The Mylan Defendants deny that Mylan Inc. is a proper party to this action. To the extent there are allegations not expressly admitted above, such allegations are denied.

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.

ANSWER: For purposes of this litigation, the Mylan Defendants do not contest personal jurisdiction or venue in West Virginia. The Mylan Defendants deny that Mylan Inc. is a proper party to this action. To the extent there are allegations not expressly admitted above, such allegations are denied.

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.

ANSWER: For purposes of this litigation, the Mylan Defendants do not contest personal jurisdiction or venue in West Virginia. The Mylan Defendants deny that Mylan Inc. is a proper party to this action. To the extent there are allegations not expressly admitted above, such allegations are denied.

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