

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

NOVEN PHARMACEUTICALS, INC. and)
HISAMITSU PHARMACEUTICAL CO., INC.)
))
Plaintiffs,)
))
v.)
))
MYLAN TECHNOLOGIES INC., MYLAN)
PHARMACEUTICALS INC., and MYLAN INC.)
))
Defendants.)
))
_____)

CASE NO.: 1:15-cv-69-IMK_

DEFENDANTS’ ANSWER TO AMENDED COMPLAINT AND COUNTERCLAIMS

Defendants Mylan Technologies, Inc. (“MTI”), Mylan Pharmaceuticals Inc. (“MPI”), and Mylan Inc. (collectively, “Defendants”) answer and respond to each of the allegations of Plaintiffs Noven Pharmaceuticals, Inc. and Hisamitsu Pharmaceutical Co., Inc. (collectively, “Plaintiffs”) Amended Complaint as follows:

THE PARTIES

1. Plaintiff Noven Pharmaceuticals, Inc. is a Delaware corporation with a principal place of business at 11960 S.W. 144th Street, Miami, Florida 33186.

ANSWER: Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 1 of the Amended Complaint and, on that basis, deny them.

2. Plaintiff Hisamitsu Pharmaceutical Co., Inc. is a Japanese corporation with a principal place of business at Saga, Tosu, Tashiroadikan-machi, 408, Japan 841-0017.

ANSWER: Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 2 of the Amended Complaint and, on that basis, deny them.

3. Plaintiff Noven Pharmaceuticals, Inc. is a wholly-owned subsidiary of Hisamitsu Pharmaceutical Co., Inc.

ANSWER: Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations contained in paragraph 3 of the Amended Complaint and, on that basis, deny them.

4. Upon information and belief, defendant MTI is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 110 Lake Street, St. Albans, Vermont 05478.

ANSWER: Admitted.

5. Upon information and belief, defendant MTI is a wholly owned subsidiary of Mylan Inc.

ANSWER: Admitted.

6. Upon information and belief, defendant MTI is engaged in the manufacture for sale of pharmaceutical products, including transdermal pharmaceutical products.

ANSWER: Defendants admit that MTI develops and manufactures pharmaceutical products for sale in the United States. To the extent not expressly admitted herein, Defendants deny the remaining allegations of paragraph 6.

7. Upon information and belief, defendant MPI is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

ANSWER: Admitted.

8. Upon information and belief, defendant MPI is a wholly owned subsidiary of Mylan Inc.

ANSWER: Admitted.

9. Upon information and belief, defendant Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having its principal place of business at 1000 Mylan Blvd., Canonsburg, Pennsylvania 15317.

ANSWER: Admitted.

10. Upon information and belief, defendant Mylan, Inc. controls and/or dominates defendants MTI and MPI.

ANSWER: Denied.

11. Upon information and belief, defendants Mylan are in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including West Virginia.

ANSWER: Defendants admit that MPI and MTI develop and manufacture pharmaceutical products for sale in the United States. To the extent not expressly admitted herein, Defendants deny the remaining allegations of paragraph 11.

NATURE OF THE ACTION

12. This is a civil action for patent infringement of U.S. Patent Nos. 6,841,716 (“the ’716 patent”) and 8,231,906 (“the ’906 patent”) (collectively, the “patents-in-suit”) arising under the United States Patent Laws, Title 35, United States Code § 100, *et. seq.*, and in particular under 35 U.S.C. § 271. This action relates to Abbreviated New Drug Application (“ANDA”) No. 206685, which Defendants filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration (“FDA”), for approval to market a generic copy of Noven’s Minivelle[®] product, which is sold in the United States.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Plaintiffs purport to bring a civil action for alleged infringement of the ’716 and ’906 patents under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.* and under 35 U.S.C. § 271. Defendants admit that ANDA No. 206685 was filed with the FDA, in compliance with 21 U.S.C. § 355(j), seeking approval for Estradiol Transdermal System USP “Twice-Weekly” (0.025 mg/day, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day) prior to the expiration of the ’716 and ’906 patents. Defendants deny that Mylan Inc. and MPI are proper parties to this action. To the extent not expressly admitted herein, Defendants deny the remaining allegations of paragraph 12.

JURISDICTION AND VENUE

13. This is a civil action for patent infringement arising under the Patent Laws of the United States, including 35 U.S.C. § 271.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Plaintiffs purport to bring a civil

action for alleged patent infringement under the Patent Laws of the United States, including 35 U.S.C. § 271. To the extent not expressly admitted herein, Defendants deny the remaining allegations of paragraph 13.

14. This Court has subject matter jurisdiction under 28 U.S.C. §§1331 and 1338(a).

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that this Court has subject matter jurisdiction over this action with respect to MTI. Defendants deny that Mylan Inc. and MPI are proper parties to this action. To the extent not expressly admitted herein, Defendants deny the remaining allegations of paragraph 14.

15. This Court has personal jurisdiction over Defendant MPI because Defendant MPI is a corporation organized under the laws of the State of West Virginia and maintains a principal place of business at 781 Chestnut Ridge Rd., Morgantown, West Virginia 26505.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent that an answer is required, Defendants admit that MPI is incorporated under the laws of the State of West Virginia and that it has a principal place of business in the State of West Virginia. Defendants deny that Mylan Inc. and MPI are proper parties to this action. For purposes of this action only, Defendants do not contest personal jurisdiction. To the extent not expressly admitted herein, Defendants deny the remaining allegations of paragraph 15.

16. This court has personal jurisdiction over Defendant MTI because Defendant MTI is a corporation organized under the laws of the State of West Virginia.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent that an answer is required, Defendants admit that MTI is incorporated under the laws of the State of West Virginia. For purposes of this action only, Defendants do not contest personal jurisdiction with respect to MTI. To the extent not expressly admitted herein, Defendants deny the remaining allegations of paragraph 16.

17. This court also has personal jurisdiction over each of the Mylan Defendants because upon information and belief (1) MTI, MPI, and Mylan Inc. are registered to do business in the State of West Virginia and share an agent for service of process in West Virginia, the Corporation Service Company, 209 West Washington Street, Charleston, West Virginia 25302; (2) Defendant Mylan Inc. and MPI have submitted to jurisdiction in this District in numerous patent cases; and (3) Defendant Mylan Inc. has purposefully availed itself of the privilege of doing business in the State of West Virginia and the Northern District of West Virginia by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including the State of West Virginia and the Northern District of West Virginia, and/or by selling, directly or through its agents, pharmaceutical products in the State of West Virginia and the Northern District of West Virginia.

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required.

For purposes of this action only, Defendants do not contest personal jurisdiction. Defendants deny that Mylan Inc. and MPI are proper parties to this action. To the extent not expressly admitted herein, Defendants deny the remaining allegations of paragraph 17.

18. Upon information and belief, MPI and MTI are registered pursuant to W. Va. Code §30-5-2 (2014) to distribute generic pharmaceutical products in West Virginia and hold current and valid “Wholesale Distributor” licenses from the West Virginia Board of Pharmacy. MPI also holds a current and valid “Manufacturer” license from the West Virginia Board of Pharmacy.

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required.

For purposes of this action only, Defendants do not contest personal jurisdiction. Defendants deny that Mylan Inc. and MPI are proper parties to this action. To the extent not expressly admitted herein, Defendants deny the remaining allegations of paragraph 18.

19. Upon information and belief, Mylan Inc. regularly does or solicits business in West Virginia, engages in other persistent courses of conduct in West Virginia, and/or derives substantial revenue from services or things used or consumed in West Virginia by Mylan Inc. or its affiliates and agents, including MTI and MPI, demonstrating that Mylan Inc. has continuous and systematic contacts with West Virginia.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required.

For purposes of this action only, Defendants do not contest personal jurisdiction. Defendants

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