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Mylan Pharmaceuticals Inc., Mylan Laboratories Limited and Mylan Inc.*

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

HORIZON PHARMA, INC., and POZEN,  
INC.,

Plaintiffs/  
Counterclaim  
Defendants,

v.

MYLAN PHARMACEUTICALS, INC.,  
MYLAN LABORATORIES LIMITED, and  
MYLAN, INC.,

Defendants/  
Counterclaim  
Plaintiffs.

No. 3:15-cv-03327-MLC-DEA

**ANSWER TO SECOND AMENDED  
COMPLAINT, SEPARATE DEFENSES,  
AND COUNTERCLAIMS BY  
DEFENDANTS MYLAN  
PHARMACEUTICALS INC.,  
MYLAN LABORATORIES LIMITED  
AND MYLAN INC.**

***DOCUMENT ELECTRONICALLY FILED***

Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc. (collectively, “Mylan”), by their undersigned attorneys, answer and respond to the Second Amended Complaint of Horizon Pharma, Inc., and Pozen, Inc. (collectively, “Plaintiffs”) on behalf of Mylan and no other parties, as follows:

### THE PARTIES

1. Plaintiff Horizon Pharma, Inc. (“Horizon”) is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 520 Lake Cook Road, Suite 520, Deerfield, Illinois 60015.

**ANSWER:** Mylan is without sufficient knowledge or information to form a belief as to the allegations of paragraph 1, and, therefore, denies those allegations.

2. Plaintiff Pozen Inc. (“Pozen”) is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 1414 Raleigh Road, Chapel Hill, North Carolina 27517.

**ANSWER:** Mylan is without sufficient knowledge or information to form a belief as to the allegations of paragraph 2, and, therefore, denies those allegations.

3. On information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, with its principal place of business at 781 Chestnut Ridge Rd., Morgantown, West Virginia 26505. On information and belief, Mylan Pharmaceuticals Inc. is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including within this district.

**ANSWER:** Mylan admits that Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Mylan denies the remaining allegations set forth in paragraph 3.

4. On information and belief, Defendant Mylan Laboratories Limited (“Mylan Limited”) was formerly known as Matrix Laboratories Limited (“Matrix Limited”). On information and belief, Defendant Mylan Limited is a corporation organized and existing under the laws of India, with its principal place of business at Plot No. 564/A/22, Road No. 92, Hyderabad 500034 Andhra Pradesh, India. On information and belief, Mylan Limited is in the

business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including within this district.

**ANSWER:** Mylan admits that Mylan Laboratories Limited is a corporation operating and existing under the laws of India with its principal place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills 500034, Hyderabad, India. Mylan denies the remaining allegations set forth in paragraph 4.

5. On information and belief, Defendant Mylan, Inc. is a corporation organized and existing under the laws of Pennsylvania, with its principal place of business at 1000 Mylan Blvd., Canonsburg, Pennsylvania 15317. On information and belief, Mylan, Inc. is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including within this district.

**ANSWER:** Mylan admits that Mylan Inc. is a corporation organized and existing under the laws of Pennsylvania. Mylan Inc.'s principal place of business is at 1000 Mylan Boulevard, Canonsburg, PA 15317. Mylan denies the remaining allegations set forth in paragraph 5.

6. On information and belief, Mylan, Inc. is the parent company of Mylan Pharmaceuticals Inc.

**ANSWER:** Mylan admits that Mylan Inc. is the parent company of Mylan Pharmaceuticals Inc.

7. On information and belief, Mylan, Inc. is the parent company of Mylan Limited.

**ANSWER:** Mylan admits that Mylan Inc. is the parent company of Mylan Laboratories Limited.

8. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Limited are within the control of Defendant Mylan, Inc. for purposes of responding to discovery in this action.

**ANSWER:** Paragraph 8 sets forth legal conclusions for which no answer is required. To the extent that an answer is deemed required, however, Mylan denies the allegations in paragraph 8.

## BACKGROUND

### The NDA

9. Horizon is the holder of New Drug Application (“NDA”) No. 022511 for VIMOVO<sup>®</sup> (naproxen and esomeprazole magnesium) Delayed-Release Tablets, in 375 mg (naproxen)/20 mg (esomeprazole magnesium) and 500 mg (naproxen)/20 mg (esomeprazole magnesium) dosage forms.

**ANSWER:** Mylan admits that there is an NDA No. 022511 for naproxen/esomeprazole magnesium products marketed under the trade name VIMOVO<sup>®</sup>. Mylan is without sufficient knowledge or information to form a belief as to the remaining allegations set forth in paragraph 9, and, therefore, denies those allegations.

10. VIMOVO<sup>®</sup> Delayed-Release Tablets are prescription drugs approved for use to relieve the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis and to decrease the risk of stomach (gastric) ulcers in patients at risk of developing stomach ulcers from treatment with non-steroidal anti-inflammatory drugs (NSAIDs). Naproxen and esomeprazole magnesium are the active ingredients in VIMOVO<sup>®</sup> Delayed-Release Tablets.

**ANSWER:** Mylan admits that there are naproxen/esomeprazole magnesium products marketed under the trade name VIMOVO<sup>®</sup>. Mylan is without sufficient knowledge or information to form a belief as to the remaining allegations set forth in paragraph 10, and, therefore, denies those allegations.

### The Patents-In-Suit

11. United States Patent No. 8,852,636 (“the ’636 patent”), entitled “Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs” was duly and legally issued by the United States Patent and Trademark Office on October 7, 2014. The claims of the ’636 patent are directed to pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen (claims 1–4, 7–10, 13–18) and methods of treating a patient for pain or inflammation comprising administration of the aforementioned compositions (claims 5–6, 11–12). A true and correct copy of the ’636 patent is attached as Exhibit A.

**ANSWER:** Mylan admits that the ’636 patent states on its face that it is entitled “Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs.” Mylan recognizes that what purports to be a copy of the ’636 patent was attached as Exhibit A to Horizon and

Pozen's Second Amended Complaint, which patent is the best source for its content. Mylan denies that the '636 patent was duly and legally issued by the U.S. Patent and Trademark Office on October 7, 2014. Paragraph 11 also contains allegations that call for legal conclusions to which no answer is required. To the extent an answer is deemed required, Mylan is without sufficient knowledge or information to form a belief as to the remaining allegations set forth in paragraph 11, and, therefore, denies those allegations.

12. Pozen owns the '636 patent by assignment. Horizon is Pozen's exclusive licensee under the '636 patent. The '636 patent will expire on May 31, 2022.

**ANSWER:** Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 12, and, therefore, denies those allegations.

13. The '636 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO<sup>®</sup> Delayed-Release Tablets.

**ANSWER:** Mylan is without sufficient knowledge or information to form a belief as to the allegations set forth in paragraph 13, and, therefore, denies those allegations.

14. United States Patent No. 8,858,996 ("the '996 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was duly and legally issued by the United States Patent and Trademark Office on October 14, 2014. The claims of the '996 patent are directed to pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen (claims 1-9, 12-15) and methods of treating a patient for pain or inflammation comprising administration of the aforementioned compositions (claims 10-11, 16-19). A true and correct copy of the '996 patent is attached as Exhibit B.

**ANSWER:** Mylan admits that the '996 patent states on its face that it is entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs." Mylan recognizes that what purports to be a copy of the '996 patent was attached as Exhibit B to Horizon and Pozen's Second Amended Complaint, which patent is the best source for its content. Mylan denies that the '996 patent was duly and legally issued by the U.S. Patent and Trademark Office on October 14, 2014. Paragraph 14 also contains allegations that call for legal conclusions to which no answer is required. To the extent an answer is deemed required, Mylan is without

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