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

HORIZON PHARMA, INC. and POZEN
INC.,

Plaintiffs,

v.

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

Defendants.

Civil Action No. 3:15-cv-03327 (MLC) (DEA)

**SECOND AMENDED COMPLAINT FOR
PATENT INFRINGEMENT**

Plaintiffs Horizon Pharma, Inc. and Pozen Inc. (collectively, “Plaintiffs”), by their attorneys, for their Complaint against Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan, Inc. (collectively, “Defendants”), allege 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.

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.

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.

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.

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.

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

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

BACKGROUND

The NDA

9. Horizon is the holder of New Drug Application (“NDA”) No. 022511 for VIMOVO[®] (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.

10. VIMOVO[®] 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[®] Delayed-Release Tablets.

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.

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.

13. The ’636 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO[®] Delayed-Release Tablets.

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.

15. Pozen owns the ’996 patent by assignment. Horizon is Pozen’s exclusive licensee under the ’996 patent. The ’996 patent will expire on May 31, 2022.

16. The '996 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

17. United States Patent No. 8,865,190 (“the '190 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 21, 2014. The claims of the '190 patent are directed to a process for preparing pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen. A true and correct copy of the '190 patent is attached as Exhibit C.

18. Pozen owns the '190 patent by assignment. Horizon is Pozen’s exclusive licensee under the '190 patent. The '190 patent will expire on May 31, 2022.

19. United States Patent No. 9,161,920 (“the '920 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 20, 2015. The claims of the '920 patent are directed to methods of reducing the incidence of NSAID-associated gastric ulcers by administering a pharmaceutical composition in unit dose form comprising naproxen and esomeprazole. A true and correct copy of the '920 patent is attached as Exhibit D.

20. Pozen owns the '920 patent by assignment. Horizon is Pozen’s exclusive licensee under the '920 patent. The '920 patent will expire on May 31, 2022.

21. The '920 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

22. United States Patent No. 9,198,888 (“the '888 patent”), entitled “Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs,” was duly and legally issued by the United States Patent and Trademark Office on December 1, 2015. The claims of the '888 patent

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