IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

POZEN INC. a Delaware corporation,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
ALPHAPHARM PTY LTD., MYLAN PHARMACEUTICALS INC., and MYLAN INC.,	)	
	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff Pozen Inc. ("Pozen") complains against Alphapharm Pty Ltd. ("Alphapharm"), Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "Defendants") and alleges the following:

The Parties

1. Pozen is a Delaware corporation, having its principal place of business at 1414 Raleigh Road, Chapel Hill, North Carolina 27517. Pozen is a specialty pharmaceutical company dedicated to developing therapeutic advancements for diseases with unmet medical needs. Pozen currently specializes in innovative drug products designed to alleviate patient pain and suffering.

2. On information and belief, Alphapharm is an Australian corporation with its principal place of business at Chase Building 2, Wentworth Park Road, Glebe, NSW Australia 2037.

3. On information and belief, Mylan Pharmaceuticals Inc. is a West Virginia corporation with its principal place of business at 781 Chestnut Ridge Rd., Morgantown, WV

26505. On information and belief Mylan Pharmaceuticals Inc. is the designated U.S. agent of Alphapharm.

4. On information and belief, Mylan Inc. is a Pennsylvania corporation with its principal place of business at 1500 Corporate Drive, Canonsburg, PA 15317.

5. On information and belief, Alphapharm and Mylan Pharmaceuticals Inc. are wholly-owned subsidiaries of Mylan Inc.

6. On information and belief, Defendants are in the business of developing, manufacturing, distributing and selling generic drug products throughout the United States, including for distribution and sale in this district.

Nature of the Case

7. This is an action for infringement of United States Patent Nos. 6,060,499 (a true and correct copy is attached hereto as Exhibit A), 6,586,458 (a true and correct copy is attached hereto as Exhibit B). This action is based on the Patent Laws of the United States as found in 35 U.S.C. § 100, *et seq.*

Jurisdiction and Venue

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(c), (d) and 1400(b).

9. This Court has personal jurisdiction over Defendants because Defendants have systematic and continuous contacts with this jurisdiction.

10. On information and belief, Defendants collaborate in the manufacture, sale and distribution of generic drug products throughout the United States and specifically in this judicial district.

Background

11. On May 9, 2000, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 6,060,499 (the '499 patent), entitled Anti-migraine Methods and Compositions Using 5-HT Agonists with Long-Acting NSAIDS. The '499 patent issued to Pozen as the assignee and is currently assigned to Pozen.

12. On July 1, 2003, the PTO issued U.S. Patent No. 6,586,458 (the '458 patent), entitled Methods of Treating Headaches Using 5-HT Agonists in Combination with Long-Acting NSAIDS. The '458 patent issued to Pozen as the assignee and is currently assigned to Pozen.

13. On April 15, 2008, the United States Food and Drug Administration ("FDA") approved Pozen's new drug application for Treximet™, NDA No. 21-926. Treximet™ is a tablet for oral administration and contains 85 mg of sumatriptan (present as a succinate) and 500 mg of naproxen sodium.

14. Treximet™ is approved for the acute treatment of migraine attacks with or without aura.

15. Pursuant to 21 U.S.C. § 355(b), Pozen submitted patent information for the '499 and '458 and patents for inclusion in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book." The FDA thereafter listed the '499 and '458 patents in the Orange Book in connection with the Treximet™ NDA.

16. On information and belief, Alphapharm filed papers with the FDA allegedly constituting an abbreviated new drug application under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use and sale of a generic version of

Treximet™. On information and belief, the FDA assigned Alphapharm's ANDA submission ANDA No. 90-872 (hereinafter "Alphapharm's ANDA").

17. Mylan Pharmaceuticals Inc. is the designated U.S. agent for Alphapharm. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Inc. actively participated in the research, creation and development of Alphapharm's generic product and in the filing of Alphapharm's ANDA.

18. On information and belief, Defendants collaborated in the submission of Alphapharm's ANDA, stand to benefit from the filing of the Alphapharm ANDA should it be approved, and have collaborated in and benefitted from the manufacture and distribution of generic drugs under other ANDAs. On information and belief, Mylan Inc. and Mylan Pharmaceuticals Inc. actively encouraged, aided, abetted and collaborated with Alphapharm in the submission of Alphapharm's ANDA and continue to do so in pursuing approval of Alphapharm's ANDA.

19. On information and belief, the product that is the subject of Alphapharm's ANDA is a tablet for oral administration that contains 85 mg sumatriptan (present as a succinate) and 500 mg naproxen sodium (hereinafter referred to as the "Generic Product").

20. On information and belief, Alphapharm intends that its Generic Product be used by consumers for the acute treatment of migraine attacks with or without aura.

21. On November 21, 2008, Pozen received a letter from counsel for Alphapharm (the "Notice Letter") advising that Alphapharm had submitted ANDA No. 90-872 and that its ANDA contained certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), commonly referred to as Paragraph IV certifications, that in Alphapharm's opinion, the '499 and

'458 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, or importation of the product that is the subject of the Alphapharm ANDA.

22. The Notice Letter also advised that Alphapharm intends to market the Generic Product before the expiration of the '499 and '458 patents.

23. The Notice Letter also included an offer of confidential access to Alphapharm's ANDA. Counsel for Pozen requested access to Alphapharm's ANDA, and thereafter Alphapharm provided what appeared to be at least a portion of Alphapharm's ANDA.

Count I – Infringement of the '499 Patent

24. Pozen incorporates by reference and repeats the allegations in paragraphs 1-23 above.

25. Defendants' submission of ANDA No. 90-872 to the FDA, including the Paragraph IV certification to the '499 patent contained therein, constitutes infringement of at least claims 9, 15, 17 and 18 of the '499 patent under 35 U.S.C. § 271(e)(2)(A).

26. Defendants' commercial manufacture, offer for sale, sale, importation or use of the Generic Product would infringe and/or induce infringement, either literally or under the doctrine of equivalents, of at least claims 9, 15, 17 and 18 of the '499 patent.

27. Upon information and belief, Defendants were aware of the '499 patent when they submitted their ANDA.

Count II – Infringement of the '458 Patent

28. Pozen incorporates by reference and repeats the allegations in paragraphs 1-27 above.

29. Defendants' submission of ANDA No. 90-872 to the FDA, including the Paragraph IV certification to the '458 patent contained therein, constitutes infringement of at least claims 1-8, 10-12, 14, 15 and 22-32 of the '458 patent under 35 U.S.C. § 271(e)(2)(A).

30. Defendants' commercial manufacture, offer for sale, sale, importation or use of the Generic Product would infringe and/or induce infringement, either literally or under the doctrine of equivalents, of at least claims 1-8, 10-12, 14, 15 and 22-32 of the '458 patent.

31. Upon information and belief, Defendants were aware of the '458 patent when they submitted their ANDA.

Prayer for Relief

In view of the foregoing, Pozen respectfully requests the following relief:

A. A judgment that Defendants' submission of ANDA No. 90-872 constitutes infringement of one or more claims of the '499 and '458 patents;

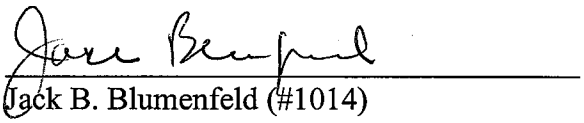
B. An order pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Defendants' ANDA shall not be earlier than the expiration date of the '499 or '458 patents, including any extensions thereof;

C. A permanent injunction under 35 U.S.C. § 271(e)(4)(B) restraining Defendants, their affiliates, officers, agents, servants, employees, and any person in active concert or participation with Defendants or any of the foregoing, from the commercial manufacture, use, import, offer to sell or sale within the United States of the Generic Product;

D. Costs and expenses incurred in pursuing this action; and

E. Any other relief the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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