IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

POZEN INC.	§	
	§	
Plaintiff,	§	
	§	
v.	§	CIVIL ACTION NO. 6:08-cv-437
	§	
PAR PHARMACEUTICAL, INC.	§	
	§	
Defendant.	§	
	§	

ORIGINAL COMPLAINT

Plaintiff Pozen Inc. ("Pozen") complains against Par Pharmaceutical, Inc. ("Par") 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, Par is a New Jersey corporation with its principal place of business at 1 Ram Ridge Road, Spring Valley, New York 10977.

3. On information and belief, Par is in the business of developing, manufacturing, distributing and selling generic drug products through the United States, including for distribution and sale in this district.

Nature of the Case

4. 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) and 7,332,183 (a true and correct copy is attached hereto as Exhibit C). 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

5. 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) and §1400(b).

6. This Court has personal jurisdiction over Par because Par has systematic and continuous contacts with this jurisdiction.

7. On information and belief, Par manufactures, sells and distributes pharmaceutical products throughout the United States and in this judicial district.

Background

8. 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.

9. 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.

10. On February 19, 2008, the PTO issued U.S. Patent No. 7,332,183 (the ’183 patent), entitled Multilayer Dosage Forms Containing NSAIDS and Triptans. The ’183 patent issued to Pozen as the assignee and is currently assigned to Pozen.

11. 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.

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

13. Pursuant to 21 U.S.C. § 355(b), Pozen submitted patent information for the ’499, ’458 and ’183 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, ’458 and ’183 patents in the Orange Book in connection with the Treximet™ NDA.

14. On information and belief, Par 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 Par’s ANDA submission ANDA No. 90-753 (hereinafter “Par’s ANDA”).

15. On information and belief, the product that is the subject of Par’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”).

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

17. On October 8, 2008, Par sent a letter to Pozen (the "Notice Letter") advising that Par had submitted ANDA No. 90-753 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 Par's opinion, the '499, '458 and '183 patents are invalid and/or will not be infringed by the manufacture, use or sale of the product that is the subject of the Par ANDA.

18. The Notice Letter also advised that Par intends to market the Generic Product before the expiration of the '499, '458 and '183 patents.

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

Count I – Infringement of the '499 Patent

20. Pozen incorporates by reference and repeats the allegations in paragraphs 1-19 above.

21. Par's submission of ANDA No. 90-753 to the FDA, including the Paragraph IV certification to the '499 patent contained therein, constitutes infringement of claims 9, 15, 17 and 18 of the '499 patent under 35 U.S.C. § 271(e)(2)(A).

22. Par's 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 claims 9, 15, 17 and 18 of the '499 patent.

23. Upon information and belief, Par was aware of the '499 patent when it submitted its ANDA.

Count II – Infringement of the '458 Patent

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

25. Par's submission of ANDA No. 90-753 to the FDA, including the Paragraph IV certification to the '458 patent contained therein, constitutes infringement of claims 1-8, 10-12, 14, 15 and 22-32 of the '458 patent under 35 U.S.C. § 271(e)(2)(A).

26. Par's 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 claims 1-8, 10-12, 14, 15 and 22-32 of the '458 patent.

27. Upon information and belief, Par was aware of the '458 patent when it submitted its ANDA.

Count III – Infringement of the '183 Patent

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

29. Par's submission of ANDA No. 90-753 to the FDA, including the Paragraph IV certification to the '183 patent contained therein, constitutes infringement of claims 1-7 and 9-20 of the '183 patent under 35 U.S.C. § 271(e)(2)(A).

30. Par's 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 claims 1-7 and 9-20 of the '183 patent.

31. Upon information and belief, Par was aware of the '183 patent when it submitted its ANDA.

Prayer for Relief

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

A. A judgment that Par's submission of ANDA No. 90-753 constitutes infringement of one or more claims of the '499, '458 and '183 patents;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Par's ANDA shall not be earlier than the expiration date of the '499, '458 or '183 patents, including any extensions thereof;

C. A permanent injunction under 35 U.S.C. § 271(e)(4)(B) restraining Par, its officers, agents, servants, employees, and any person in active concert or participation with Par 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.

Respectfully submitted,

By: /s/ Willem B. Schurrman (Collin Maloney by permission)

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