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

POZEN INC.	§	
	§	
Plaintiff,	§	
	§	
v.	§	CIVIL ACTION NO. 6:09-cv-182-LED
	§	
TEVA PHARMACEUTICALS USA, Inc.	§	PATENT CASE
	§	
Defendant.	§	
	§	

POZEN INC.'S AMENDED COMPLAINT

Plaintiff Pozen Inc. ("Pozen") complains against Teva Pharmaceuticals USA, Inc. ("Teva") 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, Teva is a Delaware corporation with its principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454-1090.

3. On information and belief, Teva is 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

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), (d) and 1400(b).

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

7. On information and belief, Teva manufactures, sells and distributes generic drug products throughout the United States, including for distribution and sale in this 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 ("NDA") 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, Teva filed papers with the FDA allegedly constituting an Abbreviated New Drug Application ("ANDA") 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 Teva's ANDA submission ANDA No. 91-146 (hereinafter "Teva's ANDA").

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

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

17. On April 15, 2009, Pozen received a letter from Teva's Senior Director of Regulatory Affairs (the "Notice Letter") advising that Teva had submitted ANDA No. 91-146 which

seeks approval to "engage in the commercial manufacture, use, or sale of Sumatriptan and Naproxen Sodium Tablets, Eq. 85 mg base/500 mg . . ." The Notice Letter further advises that Teva's ANDA contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), commonly referred to as Paragraph IV Certifications, that in Teva's opinion, the '499, '458 and '183 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 Teva's ANDA.

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

Count I – Infringement of the '499 Patent

19. Pozen incorporates by reference and repeats the allegations in paragraphs 1-18 above.

20. Teva's submission of ANDA No. 91-146 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).

21. Teva'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 at least claims 9, 15, 17 and 18 of the '499 patent.

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

Count II – Infringement of the '458 Patent

23. Pozen incorporates by reference and repeats the allegations in paragraphs 1-22 above.

24. Teva's submission of ANDA No. 91-146 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).

25. Teva'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 at least claims 1-8, 10-12, 14, 15 and 22-32 of the '458 patent.

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

Count III – Infringement of the '183 Patent

27. Pozen incorporates by reference and repeats the allegations in paragraphs 1-26 above.

28. Teva's submission of ANDA No. 91-146 to the FDA, including the Paragraph IV Certification to the '183 patent contained therein, constitutes infringement of claims 1-5, 10-14 and 17-20 of the '183 patent under 35 U.S.C. § 271(e)(2)(A).

29. Teva'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 1-5, 10-14 and 17-20 of the '183 patent.

30. Upon information and belief, Teva 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 the submission of Teva's ANDA 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 Teva's ANDA shall not be earlier than the expiration date of the '499, '458 and '183 patents, including any extensions thereof;

C. A permanent injunction under 35 U.S.C. § 271(e)(4)(B) restraining Teva, its affiliates, officers, agents, servants, employees, and any person in active concert or participation with Teva or any of the foregoing, from the commercial manufacture, use, import, offer to sell or sale within the United States of the Generic Product prior to the expiration of the '499, '458 and '183 patents, including any extensions thereof;

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

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

Respectfully submitted,

Dated: July 2, 2009

By: /s/ Stephen M. Hash

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a). As such, this motion was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed. R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email and/or fax, on this the 2nd day of July, 2009.

/s/ Stephen M. Hash