UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA

ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA UK LIMITED, Plaintiffs, v. OSMOTICA PHARMCEUTICAL CORPORATION, Defendant.	)	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited (collectively, "AstraZeneca"), for their complaint against Defendant Osmotica Pharmaceutical Corporation ("Osmotica"), hereby allege as follows:

THE PARTIES

1. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of Delaware, having its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

2. Plaintiff AstraZeneca UK Limited is a company incorporated under the Laws of England and Wales, having a registered office at 15 Stanhope Gate, W1K 1LN, London, England.

3. Upon information and belief, Osmotica is a corporation organized and existing under the laws of North Carolina, having its principal place of business at 1205 Culbreth

Drive, Suite 200, Wilmington, North Carolina 28405. Upon information and belief, Osmotica is in the business of, among other things, manufacturing, marketing and selling generic copies of branded pharmaceutical products throughout the United States.

JURISDICTION AND VENUE

4. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391(c), 1391(d), and 1400(b).

5. This Court has personal jurisdiction over Osmotica because Osmotica has purposely availed itself of the benefits and protections of the laws of North Carolina such that it should reasonably anticipate being haled into court here. In addition, Osmotica has had continuous and systematic contacts with this judicial district, including, on information and belief, maintaining its principle place of business in Wilmington, North Carolina, selling pharmaceutical products in North Carolina and deriving substantial revenues from those sales. Thus, Osmotica Pharmaceuticals is subject to general jurisdiction in North Carolina.

6. Nine related lawsuits are currently pending in the United Stated District Court for the District of New Jersey. On July 28, 2008, AstraZeneca filed suit in this Court against Handa Pharmaceuticals, LLC and John Doe Entity ("Handa") seeking a judgment that its U.S. Patent Nos. 4,879,288 (the "'288 patent") and 5,948,437 (the "'437 patent," a copy of which is attached hereto as Exhibit A) are infringed by Handa's filing of its ANDA No. 90-482. *See AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Handa Pharms., LLC and John Doe Entity*, Case No. 08-3773 (D.N.J.). On September 26, 2008, AstraZeneca filed suit in this Court against Accord Healthcare, Inc., Accord Health Care, Inc., Accord Healthcare Ltd., and Intas

Pharmaceuticals, Ltd. ("Accord") seeking a judgment that the '437 patent is infringed by Accord's filing of its ANDA No. 90-681. *See AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Accord Healthcare, Inc. and Intas Pharms., Ltd,* Case No. 08-4804 (D.N.J.). On October 28, 2008, AstraZeneca filed another suit in this Court against Handa seeking a judgment that both the '288 and '437 patents are infringed by Handa's amendments to its ANDA No. 90-482. *See AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Handa Pharms., LLC and John Doe Entity,* Case No. 08-5328 (D.N.J.). On December 8, 2008, AstraZeneca filed another suit in this Court against Handa seeking a judgment that both the '288 and '437 patents are infringed by another Handa amendment to its ANDA No. 90-482. *See AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Handa Pharms., LLC and John Doe Entity,* Case No. 08-5997 (D.N.J.). On January 9, 2009, AstraZeneca filed suit in this Court against Biovail Laboratories International SRL, Biovail Corporation and BTA Pharmaceuticals, Inc. ("Biovail") seeking a judgment that the '288 and '437 patents are infringed by Biovail's filing of its ANDA No. 90-882. *See AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Biovail Labs Int'l SRL, Biovail Corp. and BTA Pharms., Inc.,* Case No. 09-0128 (D.N.J.). On. February 10, 2009, AstraZeneca filed another suit in this Court against Accord seeking a judgment that the '437 patent is infringed by Accord's amendment to its ANDA No. 90-681. *See AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Accord Healthcare, Inc. and Intas Pharms., Ltd,* Case No. 09-0619 (D.N.J.). On April 8, 2010, AstraZeneca filed suit in this Court against Anchen Pharmaceuticals ("Anchen") seeking a judgment that the '437 patent is infringed by Accord's filing of its ANDA No. 90-757. *See AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Anchen Pharmaceuticals Inc.,* Case No. 10-1835 (D.N.J.). On August 16, 2010, AstraZeneca filed suit in this Court against Osmotica seeking a judgment that the '437 patent is infringed by Osmotica's filing of its

ANDA No. 201424. *See AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Osmotica Pharmaceutical Corp.*, Case No. 10-4203 (D.N.J.). On August 16, 2010, AstraZeneca filed suit in this Court against Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. (collectively "Torrent") seeking a judgment that the '437 patent is infringed by Torrent's filing of its ANDA No. 201996. *See AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc.*, Case No. 10-4205 (D.N.J.). AstraZeneca believes this action would be best adjudicated in the District of New Jersey and should be coordinated and proceed concurrently with these pending actions, however Osmotica has rebuffed AstraZeneca's request to enter into a stipulation and proposed order not to dispute AstraZeneca's assertion of personal jurisdiction over Osmotica in New Jersey, thus necessitating this protective suit.

CLAIMS FOR RELIEF

Count 1: Direct Infringement By Osmotica

7. AstraZeneca realleges paragraphs 1-6 above as if set forth specifically herein.

8. Plaintiff AstraZeneca Pharmaceuticals LP is the holder of New Drug Application ("NDA") No. 22-047, by which the FDA first granted approval for 50 mg, 150 mg, 200 mg, 300 mg and 400 mg extended release tablets containing the active ingredient quetiapine (11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl] dibenzo [b,f][1,4] thiazepine) fumarate. The quetiapine fumarate extended release tablets described in NDA No. 22-047 are sold by AstraZeneca in the United States under the trademark SEROQUEL XR®.

9. Plaintiff AstraZeneca Pharmaceuticals LP is the owner of the '288 patent, entitled "Novel Dibenzothiazepine Antipsychotic," which was duly and legally issued by the United States Patent and Trademark Office on November 7, 1989 upon assignment from the

inventors Edward J. Warawa and Bernard M. Migler. The ‘288 patent claims, *inter alia*, quetiapine fumarate, the active ingredient of SEROQUEL XR®, and methods of using that compound.

10. The ‘288 patent will expire on September 26, 2011.

11. Plaintiff AstraZeneca UK Limited is the owner of the ’437 patent, entitled “Pharmaceutical Compositions Using Thiazepine,” which was duly and legally issued by the United States Patent and Trademark Office on September 7, 1999 upon assignment from the inventors Bhavnish V. Parikh, Robert J. Timko and William J. Addicks. The ’437 patent claims, *inter alia*, sustained release formulations of quetiapine fumarate, including SEROQUEL XR® extended release tablets, and processes for preparing and using such formulations.

12. The ’437 patent will expire on May 28, 2017.

13. By letter dated July 30, 2010 purporting to be a notice pursuant to 21 U.S.C. § 355 (j)(2)(B) (the “Notice Letter”), Osmotica notified AstraZeneca that it had submitted ANDA No. 201424 to the FDA seeking the approval of the FDA to commercially manufacture, market, use and sell, prior to the expiration of the ’437 patents, quetiapine fumarate extended release tablets in 200 mg, 300 mg and 400 mg strengths as generic versions of AstraZeneca’s SEROQUEL XR® 200 mg, 300 mg and 400 mg extended release tablets.

14. In the Notice Letter, Osmotica alleged that certain claims of the ’437 patent will not be infringed by its proposed generic quetiapine fumarate extended release tablets. Osmotica did not allege in the Notice Letter that its proposed generic quetiapine fumarate extended release tablets will not infringe claims 1-2 and 11-14 of the ’437 patent.

15. Osmotica also alleged in the Notice Letter that claims 1-2 and 10-15 of the ’437 patent are invalid for failure to meet the 35 U.S.C. §103(a) obviousness requirement.

16. Osmotica has infringed the ’437 patent under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 201424 seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in the ’437 patent, or the use of which is claimed in the ’437 patent, prior to the expiration of that patent.

17. The quetiapine fumarate extended release tablets for which Osmotica seeks approval under ANDA No. 201424 will infringe one or more claims of the ’437 patent under 35 U.S.C. §271(a).

18. The commercial manufacture, use, sale or offer for sale within the United States, or the importation into the United States, of Osmotica’s quetiapine fumarate extended release tablets will infringe one or more claims of the ’437 patent under 35 U.S.C. § 271(a).

19. AstraZeneca is entitled to full relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 201424 be a date that is not earlier than the later of May 28, 2017, the expiration date of the ’437 patent, or the expiration of any other exclusivity to which AstraZeneca is or becomes entitled.

Count 2: Exceptional Case

20. AstraZeneca realleges paragraphs 1-19 as if set forth specifically herein.

21. Prior to filing ANDA No. 201424, defendant was aware of the existence of the ’437 patent, and, upon information and belief, was aware that the filing of ANDA No. 201424, including a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV”) with respect to the ’437 patents, infringed that patent.

22. The opinions set forth in the Notice Letter that the ’437 patent is invalid are devoid of an objective, good faith basis in either the facts or the law.

23. This case is an exceptional one, and AstraZeneca is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the ’437 patent remains valid and enforceable, and that this patent has been infringed by Defendant;

(b) A judgment declaring that the effective date of any approval of ANDA No. 201424 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date that is not earlier than the later of May 28, 2017, the expiration date of the ’437 patent, or the expiration of any other exclusivity to which AstraZeneca is or becomes entitled;

(c) A permanent injunction against any infringement of the ’437 patent by Defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them;

(d) A judgment that this is an exceptional case, and that Plaintiffs are entitled to an award of its reasonable attorney fees pursuant to 35 U.S.C. § 285;

(e) To the extent that Defendants have committed any acts with respect to the subject matter claimed in the ’437 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts, which this Court should treble pursuant to 35 U.S.C. § 284;

(f) Costs and expenses in this action; and

(g) Such other relief as this Court may deem proper.

Dated: September 13, 2010

Respectfully submitted,

By: /s/ Hill Allen

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