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17 AstraZeneca Pharmaceuticals LP and
AstraZeneca UK Limited

18 **UNITED STATES DISTRICT COURT**
19 **FOR THE CENTRAL DISTRICT OF CALIFORNIA**

20 ASTRAZENECA PHARMACEUTICALS LP and
21 ASTRAZENECA UK LIMITED,

22 Plaintiffs,

23 v.

24 ANCHEN PHARMACEUTICALS, INC. and
25 ANCHEN, INC.,

26 Defendants.

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CLERK U.S. DISTRICT COURT
CENTRAL DIST. OF CALIF.
SANTA ANA

FILED

SACV 10-590 AG(RNBx)

Civil Action No.: _____

**COMPLAINT FOR
PATENT INFRINGEMENT**

1 Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca UK Limited
2 (collectively, "AstraZeneca"), for their complaint against Defendants Anchen
3 Pharmaceuticals, Inc. ("Anchen Pharmaceuticals") and Anchen, Inc. ("Anchen
4 Holding") (collectively "Defendants"), hereby allege as follows:
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6

7 **THE PARTIES**

8 1. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership
9 organized under the laws of Delaware, having its principal place of business at 1800
10 Concord Pike, Wilmington, Delaware 19803.
11

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

16 3. Upon information and belief, Anchen Pharmaceuticals is a
17 corporation organized and existing under the laws of California, having its principal
18 place of business at 9601 Jeronimo Road, Irvine, California 92618. Upon information
19 and belief, Anchen Pharmaceuticals is in the business of, among other things,
20 manufacturing and selling generic copies of branded pharmaceutical products
21 throughout the United States.
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24 4. Upon information and belief, Anchen Holding is a corporation
25 organized and existing under the laws of Delaware, having its principal place of
26 business at 9601 Jeronimo Road, Irvine, California 92618. Upon information and
27 belief, Anchen Holding is in the business of, among other things, manufacturing and
28

1 selling generic copies of branded pharmaceutical products throughout the United
2 States.

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4 **JURISDICTION AND VENUE**

5 5. This action arises under the Patent Laws of the United States and
6 the Food and Drug Laws of the United States, Titles 35 and 21, United States Code.
7
8 Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court
9 under 28 U.S.C. §§ 1391(c), 1391(d), and 1400(b).

10 6. This Court has personal jurisdiction over Anchen Pharmaceuticals
11 because Anchen Pharmaceuticals has purposely availed itself of the benefits and
12 protections of the laws of California such that it should reasonably anticipate being
13 haled into court here. In addition, Anchen Pharmaceuticals has had continuous and
14 systematic contacts with this judicial district, including, on information and belief
15 maintaining its principal place of business in Irvine, California, selling pharmaceutical
16 products in California and deriving substantial revenues from those sales. Thus,
17 Anchen Pharmaceuticals is subject to personal jurisdiction in California.

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21 7. This Court has personal jurisdiction over Anchen Holding because
22 Anchen Holding has purposely availed itself of the benefits and protections of the
23 laws of California such that it should reasonably anticipate being haled into court here.
24 In addition, Anchen Holding has had continuous and systematic contacts with this
25 judicial district, including, on information and belief, maintaining its principal place of
26 business in Irvine, California and selling pharmaceutical products in California and
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1 deriving substantial revenues from those sales. Thus, Anchen Holding is subject to
2 personal jurisdiction in California.

3
4 8. Upon information and belief, Anchen Pharmaceuticals and Anchen
5 Holding are closely related and acts of each have been closely coordinated; both
6 companies conduct business in the generic pharmaceutical industry; employees from
7 both companies are intermingled; both companies share the same address; both
8 companies share officers and employees, including Margaret Choy, Senior Vice
9 President of Regulatory Affairs, the contact person identified on Anchen
10 Pharmaceuticals' Paragraph IV Notice Letter, which is discussed below; and the
11 companies collaborate in the manufacture, marketing, and sale of pharmaceutical
12 products, including generic drug products manufactured and sold throughout the
13 United States pursuant to approved abbreviated new drug applications.

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17 9. In addition, during the prosecution of Anchen Pharmaceuticals'
18 trademark application for the word mark ANCHEN (serial no. 77051871),
19 representatives for Anchen Pharmaceuticals stated that "Anchen Pharmaceuticals, Inc.
20 and [Anchen Holding], though separate legal entities, constitute a single source to the
21 relevant public, and there is unity of control with respect to the nature and quality of
22 the goods."
23

24
25 10. Seven related lawsuits are currently pending in the United States
26 District Court for the District of New Jersey. On July 28, 2008, AstraZeneca filed suit
27 in the District of New Jersey against Handa Pharmaceuticals, LLC and John Doe
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1 Entity (“Handa”) seeking a judgment that its U.S. Patent Nos. 4,879,288 (the “’288
2 patent”) and 5,948,437 (the “’437 patent,” a copy of which is attached hereto as
3 Exhibit A) are infringed by Handa’s filing of its ANDA No. 90-482. *See AstraZeneca*
4 *Pharms. LP and AstraZeneca UK Ltd. v. Handa Pharms., LLC and John Doe Entity,*
5 *Case No. 08-3773 (D.N.J.).* On September 26, 2008, AstraZeneca filed suit in the
6 District of New Jersey against Accord Healthcare, Inc., Accord Health Care, Inc.,
7 Accord Healthcare Ltd., and Intas Pharmaceuticals, Ltd. (“Accord”) seeking a
8 judgment that the ’437 patent is infringed by Accord’s filing of its ANDA No. 90-681.
9 *See AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Accord Healthcare, Inc.*
10 *and Intas Pharms., Ltd,* Case No. 08-4804 (D.N.J.). On October 28, 2008,
11 AstraZeneca filed another suit in the District of New Jersey against Handa seeking a
12 judgment that both the ’288 and ’437 patents are infringed by Handa’s amendments to
13 its ANDA No. 90-482. *See AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v.*
14 *Handa Pharms., LLC and John Doe Entity,* Case No. 08-5328 (D.N.J.). On December
15 8, 2008, AstraZeneca filed another suit in the District of New Jersey against Handa
16 seeking a judgment that both the ’288 and ’437 patents are infringed by another Handa
17 amendment to its ANDA No. 90-482. *See AstraZeneca Pharms. LP and AstraZeneca*
18 *UK Ltd. v. Handa Pharms., LLC and John Doe Entity,* Case No. 08-5997 (D.N.J.).
19 On January 9, 2009, AstraZeneca filed suit in the District of New Jersey against
20 Biovail Laboratories International SRL, Biovail Corporation and BTA
21 Pharmaceuticals, Inc. (“Biovail”) seeking a judgment that the ’288 and ’437 patents
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1 are infringed by Biovail's filing of its ANDA No. 90-882. *See AstraZeneca Pharms.*
2 *LP and AstraZeneca UK Ltd. v. Biovail Labs Int'l SRL, Biovail Corp. and BTA*
3 *Pharms., Inc.*, Case No. 09-0128 (D.N.J.). On February 10, 2009, AstraZeneca filed
4 another suit in the District of New Jersey against Accord seeking a judgment that the
5 '437 patent is infringed by Accord's amendment to its ANDA No. 90-681. *See*
6 *AstraZeneca Pharms. LP and AstraZeneca UK Ltd. v. Accord Healthcare, Inc. and*
7 *Intas Pharms., Ltd.*, Case No. 09-0619 (D.N.J.). Each of these actions is assigned to
8 the Honorable Joel A. Pisano and Magistrate Judge Tonianne J. Bongiovanni and are
9 coordinated for discovery and claim construction purposes. On April 8, 2010,
10 AstraZeneca filed suit in the District of New Jersey against Anchen Pharmaceuticals
11 and Anchen Holding seeking a judgment that the '437 patent is infringed by Anchen's
12 filing of its ANDA No. 90-757. *See AstraZeneca Pharms. LP and AstraZeneca UK*
13 *Ltd. v. Anchen Pharmaceuticals, Inc. and Anchen, Inc.*, Case No. 10-1835 (D.N.J.).
14 AstraZeneca believes this action would be best adjudicated in the District of New
15 Jersey and should be coordinated and proceed concurrently with these related, pending
16 actions. Counsel for Defendants has indicated that Defendants will not move to
17 dismiss the New Jersey complaint for lack of personal jurisdiction. However, on
18 information and belief, Defendants will not consent to personal jurisdiction in New
19 Jersey. This leaves AstraZeneca with no choice but to file this protective suit.
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1 **CLAIMS FOR RELIEF**

2 **Count 1: Direct Infringement By Anchen Pharmaceuticals**

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4 11. AstraZeneca realleges paragraphs 1-10 above as if set forth
5 specifically herein.

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7 12. Plaintiff AstraZeneca Pharmaceuticals LP is the holder of New
8 Drug Application (“NDA”) No. 22-047, by which the FDA first granted approval for
9 50 mg, 150 mg, 200 mg, 300 mg and 400 mg extended release tablets containing the
10 active ingredient quetiapine (11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl] dibenzo
11 [b,f][1,4] thiazepine) fumarate. The quetiapine fumarate extended release tablets
12 described in NDA No. 22-047 are sold by AstraZeneca in the United States under the
13 trademark SEROQUEL XR[®].
14

15
16 13. Plaintiff AstraZeneca Pharmaceuticals LP is the owner of the ‘288
17 patent, entitled “Novel Dibenzothiazepine Antipsychotic,” which was duly and legally
18 issued by the United States Patent and Trademark Office on November 7, 1989 upon
19 assignment from the inventors Edward J. Warawa and Bernard M. Migler. The ‘288
20 patent claims, *inter alia*, quetiapine fumarate, the active ingredient of SEROQUEL
21 XR[®], and methods of using that compound.
22

23
24 14. The ‘288 patent will expire on September 26, 2011.

25
26 15. Plaintiff AstraZeneca UK Limited is the owner of the ‘437 patent,
27 entitled “Pharmaceutical Compositions Using Thiazepine,” which was duly and
28 legally issued by the United States Patent and Trademark Office on September 7, 1999

1 upon assignment from the inventors Bhavnish V. Parikh, Robert J. Timko and
2 William J. Addicks. The '437 patent claims, *inter alia*, sustained release formulations
3 of quetiapine fumarate, including SEROQUEL XR[®] extended release tablets, and
4 processes for preparing and using such formulations.
5

6 16. The '437 patent will expire on May 28, 2017.
7

8 17. By letter dated March 26, 2010 purporting to be a notice pursuant
9 to 21 U.S.C. § 355 (j)(2)(B) (the "Notice Letter"), Anchen Pharmaceuticals notified
10 AstraZeneca that it had submitted ANDA No. 90-757 to the FDA seeking the
11 approval of the FDA to commercially manufacture, use and sell, prior to the
12 expiration of the '437 patent, quetiapine fumarate extended release tablets in 150, 200,
13 300 and 400 mg strengths as generic versions of AstraZeneca's SEROQUEL XR[®]
14 150, 200, 300 and 400 mg extended release tablets.
15
16

17 18. In the Notice Letter, Anchen Pharmaceuticals alleged that claims
18 3-9 and 12 of the '437 patent will not be infringed by Anchen Pharmaceuticals'
19 proposed generic quetiapine fumarate extended release tablets. Anchen
20 Pharmaceuticals did not allege in the Notice Letter that its proposed generic
21 quetiapine fumarate extended release tablets will not infringe any claim of the '288
22 patent and claims 1-2, 10, and 13-15 of the '437 patent.
23
24

25 19. Anchen Pharmaceuticals also alleged in the Notice Letter that
26 claims 1-15 of the '437 patent are invalid as obvious.
27
28

1 20. Anchen Pharmaceuticals has infringed the '437 patent under 35
2 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-757 seeking approval from the FDA to
3 engage in the commercial manufacture, use or sale of a drug claimed in the '437
4 patent, or the use of which is claimed in the '437 patent, prior to the expiration of that
5 patent.
6

7
8 21. The quetiapine fumarate extended release tablets for which Anchen
9 Pharmaceuticals seeks approval under ANDA No. 90-757 will infringe one or more
10 claims of the '437 patent under 35 U.S.C. §271(a).
11

12 22. The commercial manufacture, use, sale or offer for sale within the
13 United States, or the importation into the United States, by Anchen Pharmaceuticals
14 of the quetiapine fumarate extended release tablets that are the subject of ANDA No.
15 90-757 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).
16

17 23. AstraZeneca is entitled to full relief provided by 35 U.S.C. §
18 271(e)(4), including an order of this Court that the effective date of the approval of
19 ANDA No. 90-757 be a date that is not earlier than the later of May 28, 2017, the
20 expiration date of the '437 patent, or the expiration of any other exclusivity to which
21 AstraZeneca is or becomes entitled.
22

23
24 **Count 2: Direct Infringement By Anchen Holding**

25 24. AstraZeneca realleges paragraphs 1-23 above as if set forth
26 specifically herein.
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1 25. Upon information and belief, Anchen Holding initiates, directs and
2 controls the activities of Anchen Pharmaceuticals with regard to ANDA No. 90-757
3 and the quetiapine fumarate extended release tablets described therein.
4

5 26. Upon information and belief, Anchen Holding, through Anchen
6 Pharmaceuticals as its agent, initiated, directed and controlled the preparation and
7 filing of ANDA No. 90-757 with the FDA.
8

9 27. Upon information and belief, Anchen Holding has infringed the
10 '437 patent under 35 U.S.C. § 271(e)(2)(A) by initiating, directing and controlling the
11 preparation and filing of ANDA No. 90-757.
12

13 28. Upon information and belief, in the event that the FDA approves
14 ANDA No. 90-757, Anchen Holding stands to benefit directly from such approval by
15 being able to commercially manufacture and distribute the quetiapine fumarate
16 extended release tablets that are the subject of the ANDA.
17

18 29. The quetiapine fumarate extended release tablets for which Anchen
19 Holding, through Anchen Pharmaceuticals as its agent, seeks approval under ANDA
20 No. 90-757 will infringe one or more claims of the '437 patent under 35 U.S.C.
21 §271(a).
22

23 30. The commercial manufacture, use, sale or offer for sale within the
24 United States, or the importation into the United States, by Anchen Holding of the
25 quetiapine fumarate extended release tablets that are the subject of ANDA No. 90-757
26 will infringe one or more claims of the '437 patent under 35 U.S.C. § 271(a).
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28

1 31. AstraZeneca is entitled to full relief provided by 35 U.S.C. §
2 271(e)(4), including an order of this Court that the effective date of the approval of
3 ANDA No. 90-757 be a date that is not earlier than the later of May 28, 2017, the
4 expiration date of the '437 patent, or the expiration of any other exclusivity to which
5 AstraZeneca is or becomes entitled.
6

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8 **Count 3: Inducement of Infringement By Anchen Holding**

9 32. AstraZeneca realleges paragraphs 1-31 above as if set forth
10 specifically herein.
11

12 33. Anchen Pharmaceuticals has directly infringed the '437 patent under
13 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 90-757 seeking FDA approval under
14 21 U.S.C. § 355(j) to engage in the commercial manufacture, use or sale of a drug
15 claimed in the '437 patent, or the use of which is claimed in the '437 patent, prior to
16 the expiration of the patent.
17

18 34. Upon information and belief, Anchen Holding knowingly and
19 intentionally induced and/or aided and abetted Anchen Pharmaceuticals in the
20 preparation and filing of ANDA No. 90-757.
21

22 35. Upon information and belief, Anchen Holding knowingly and
23 intentionally induced and/or aided and abetted Anchen Pharmaceuticals in providing
24 information and materials to the FDA in connection with ANDA No. 90-757.
25

26 36. Upon information and belief, Anchen Holding knowingly and
27 intentionally induced and/or aided and abetted Anchen Pharmaceuticals in the
28

1 development of the quetiapine fumarate extended release tablets that are the subject of
2 ANDA No. 90-757, and that will infringe the '437 patent under 35 U.S.C. § 271(a).

3
4 37. Upon information and belief, Anchen Holding has, under 35
5 U.S.C. § 271(b) induced Anchen Pharmaceuticals' direct infringement of the '437
6 patent by knowingly and intentionally inducing and/or aiding and abetting the
7 preparation and filing of ANDA No. 90-757.
8

9 **Count 4: Exceptional Case**

10 38. AstraZeneca realleges paragraphs 1-37 as if set forth specifically
11 herein.
12

13 39. Prior to filing ANDA No. 90-757, defendants were aware of the
14 existence of the '437 patent, and, upon information and belief, was aware that the
15 filing of ANDA No. 90-757, including a certification pursuant to 21 U.S.C. §
16 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '437 patents, infringed that
17 patent.
18

19
20 40. The opinions set forth in the Notice Letter that the '437 patent is
21 invalid are devoid of an objective, good faith basis in either the facts or the law.
22

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

25 **PRAYER FOR RELIEF**

26 WHEREFORE, Plaintiffs respectfully request the following relief:
27
28

1 (a) A judgment declaring that the '437 patent remains valid and
2 enforceable, and that this patent has been infringed by Defendants;
3

4 (b) A judgment declaring that the effective date of any approval of
5 ANDA No. 90-757 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. § 355(j)) be a date that is not earlier than the later of May 28, 2017, the
7 expiration date of the '437 patent, or the expiration of any other exclusivity to which
8 AstraZeneca is or becomes entitled;
9

10 (c) A permanent injunction against any infringement of the '437
11 patent by Defendants, their officers, agents, attorneys, and employees, and those
12 acting in privity or concert with them;
13

14 (d) A judgment that this is an exceptional case, and that Plaintiffs are
15 entitled to an award of its reasonable attorney fees pursuant to 35 U.S.C. § 285;
16

17 (e) To the extent that Defendants have committed any acts with
18 respect to the subject matter claimed in the '437 patent, other than those acts expressly
19 exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts, which this
20 Court should treble pursuant to 35 U.S.C. § 284;
21

22 (f) Costs and expenses in this action; and
23

24 (g) Such other relief as this Court may deem proper.
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1 Dated: May 7, 2010

Respectfully submitted,

2
3 By: 

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