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LOS ANGELES

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8

9 UNITED STATES DISTRICT COURT
10 CENTRAL DISTRICT OF CALIFORNIA

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11
12 NOVARTIS PHARMACEUTICALS
13 CORPORATION, a Delaware
corporation, NOVARTIS
14 INTERNATIONAL AG, a Swiss
corporation, and NOVARTIS
15 INTERNATIONAL
PHARMACEUTICAL LTD., a
16 Bermuda corporation,

17 Plaintiffs,

18 v.

19 ANCHEN PHARMACEUTICALS,
20 INC., a California Corporation,

21 Defendant.
22

CV09-2929 CAS (W/)

CASE NO.

COMPLAINT FOR
DECLARATORY JUDGMENT,
DAMAGES AND INJUNCTIVE
RELIEF FOR INFRINGEMENT
OF U.S. PATENT NO. 6,106,864
UNDER 35 U.S.C. § 271

23
24 Plaintiffs Novartis Pharmaceuticals Corporation ("NPC"), Novartis
25 International AG ("Novartis AG"), and Novartis International Pharmaceutical, Ltd.
26 ("Novartis International") (collectively, "Novartis"), by their undersigned attorneys,
27 bring this action against Defendant, Anchen Pharmaceuticals, Inc. ("Anchen"), and
28 allege as follows:

SUMMARY OF ACTION

1
2 1. This is an action for patent infringement under the patent laws of the
3 United States, Title 35 of the United States Code, arising from Anchen’s filing
4 Abbreviated New Drug Application (“ANDA”) No. 91-190 with the United States
5 Food and Drug Administration (“FDA”) seeking approval to commercially market a
6 generic version of Novartis’s ENABLEX® drug product.

7
8 **PARTIES**

9 2. Plaintiff NPC is a corporation organized and existing under the laws of
10 the State of Delaware, with its principal place of business at One Health Plaza, East
11 Hanover, New Jersey 07936.

12 3. Plaintiff Novartis AG is a corporation organized and existing under the
13 laws of Switzerland, with an office and place of business at Lichtstrasse 35, CH 4002,
14 Basel, Switzerland.

15 4. Plaintiff Novartis International is a corporation organized and existing
16 under the laws of Bermuda, with an office and place of business at Hurst Home, 12
17 Trott Road, Hamilton HM LX, Bermuda.

18 5. On information and belief, Defendant Anchen is a corporation organized
19 and existing under the laws of the State of California, with its principal place of
20 business at 9601 Jeronimo Road, Irvine, California 92618.

21 6. On information and belief, Anchen is in the business of making and
22 selling generic pharmaceutical products which it distributes in the State of California
23 and throughout the United States.

24
25 **JURISDICTION AND VENUE**

26 7. This Court has jurisdiction over the subject matter of this action pursuant
27 to 28 U.S.C. §§ 1331 and 1338(a) and 2201 and 2202.

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1 8. This Court has personal jurisdiction over Anchen by virtue of, *inter alia*,
2 the fact that it is a corporation organized and existing under the laws of the State of
3 California.

4 9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and
5 1400(b).

6
7 **FACTUAL BACKGROUND**

8 10. United States Patent No. 6,106,864 (“the ‘864 Patent”), entitled
9 “Pharmaceutical Formulations Containing Darifenacin”, was duly and lawfully issued
10 on August 22, 2000 to inventors Thomas Francis Dolan, Michael John Humphrey, and
11 Donald John Nichols. A copy of the ‘864 Patent is attached hereto as Exhibit A.
12 Novartis International is the owner by assignment of all rights, title and interest in and
13 to the ‘864 Patent.

14 11. NPC holds an approved New Drug Application (“NDA”) under Section
15 505(a) of the Federal Food, Drug and Cosmetic Act (“FFDCA”), 21 U.S.C. § 355(a),
16 for darifenacin 7.5 mg and 15 mg extended release tablets (NDA No. 21-513), which
17 it sells under the trademark ENABLEX®. The claims of the ‘864 Patent cover, *inter*
18 *alia*, ENABLEX® and its method of use.

19 12. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the
20 ‘864 Patent is listed in the FDA publication, “Approved Drug Products with
21 Therapeutic Equivalence Evaluations” (the “Orange Book”), with respect to
22 ENABLEX®.

23 13. Upon information and belief, pursuant to Section 505(j) of the FFDCA
24 (21 U.S.C. § 355(j)), Anchen filed ANDA No. 91-190 for darifenacin hydrobromide
25 extended release tablets, seeking approval to engage in the commercial manufacture,
26 use, sale, offer for sale or importation of darifenacin hydrobromide extended release
27 tablets 7.5 mg and 15 mg (“Anchen’s ANDA Products”), before the ‘864 Patent
28 expires.

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1 14. Upon information and belief, Anchen's ANDA No. 91-190 contained
2 certifications pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV), stating that, in Anchen's
3 opinion, the claims of the '864 Patent are invalid, unenforceable, and/or will not be
4 infringed by the commercial manufacture, use or sale of Anchen's ANDA Products.

5 15. By letter dated March 16, 2009, Anchen sent written notice of its ANDA
6 filing to Novartis. The notice alleges that the claims of the '864 Patent are invalid,
7 unenforceable, and/or will not be infringed by Anchen. Anchen's notice also
8 informed Novartis that Anchen seeks approval to market Anchen's ANDA Products
9 before the '864 Patent expires.

10 16. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii)
11 within 45 days of Novartis's receipt of Anchen's notice.

12 17. Upon information and belief, Anchen intends to engage in the
13 commercial manufacture, use, sale or offer for sale of Anchen's ANDA Products
14 immediately upon receiving FDA approval to do so.

15
16 **GENERAL ALLEGATIONS**

17 18. Plaintiffs repeat and reallege the allegations of paragraphs 1-16 as though
18 fully set forth herein.

19 19. Anchen's submission of its ANDA to obtain approval to engage in the
20 commercial manufacture, use, sale, offer for sale or importation of Anchen's ANDA
21 Products, prior to the expiration of the '864 Patent, constitutes infringement of one or
22 more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

23 20. Unless enjoined by this Court, Anchen, upon FDA approval of Anchen's
24 ANDA, will infringe the '864 Patent by making, using, offering to sell, importing and
25 selling Anchen's ANDA Products in the United States, and by actively inducing and
26 contributing to infringement by others.

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1 21. Actual commercial manufacture, use, sale or offer for sale of Anchen's
2 ANDA Products prior to the expiration of the '864 Patent would constitute
3 infringement of such patent under 35 U.S.C. § 271. ANDA No. 91-190 and Anchen's
4 intention to engage in the commercial manufacture, use, sale or offer for sale of
5 Anchen's ANDA Products upon receiving FDA approval create an actual case or
6 controversy with respect to infringement of the '864 Patent.

7 22. Anchen had notice of the '864 Patent at the time of its infringement.
8 Anchen's infringement has been, and continues to be, willful and deliberate.

9 23. Plaintiffs will be substantially and irreparably damaged and harmed if
10 Anchen's infringement of the '864 Patent is not enjoined.

11 24. Plaintiffs do not have an adequate remedy at law.

12 25. This case is an exceptional one, and Plaintiffs are entitled to an award of
13 their reasonable attorneys' fees under 35 U.S.C. § 285.

14
15 **PRAYER FOR RELIEF**

16 Wherefore, Plaintiffs NPC, Novartis AG and Novartis International respectfully
17 request the following relief:

18 (A) A judgment declaring that Defendant Anchen has infringed the '864
19 Patent by submitting the aforementioned ANDA, and that Defendant's making, using,
20 selling, offering to sell, or importing of Anchen's ANDA Products will infringe the
21 '864 Patent;

22 (B) A judgment ordering that the effective date of the FDA approval of
23 Defendant's ANDA be a date which is not earlier than the expiration of the '864
24 Patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

25 (C) A judgment permanently enjoining Defendant and its officers, agents,
26 attorneys and employees, and those acting in privity or concert with them, from
27 making, using, selling, offering to sell, or importing Anchen's ANDA Products until
28

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1 after the expiration of the '864 Patent, or any later expiration of exclusivity to which
2 Plaintiffs are or become entitled;

3 (D) If Defendant engages in the commercial manufacture, use, importation
4 into the United States, sale, or offer for sale of Anchen's ANDA Products prior to the
5 expiration of the '864 Patent or any later expiration of exclusivity to which Plaintiffs
6 are or become entitled, a judgment awarding damages to Plaintiffs resulting from such
7 infringement, increased to treble the amount found or assessed, together with interest;


8 (E) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C.
9 § 285;

10 (F) Costs and expenses in this action; and

11 (G) Such further and other relief as this Court may deem just and proper.

12
13
14 DATED: April 27, 2009

Respectfully submitted,
KAYE SCHOLER LLP

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16
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