IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS INTERNATIONAL AG, and NOVARTIS INTERNATIONAL PHARMACEUTICAL, LTD., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	)	Civil Action No. _____

COMPLAINT

Plaintiffs Novartis Pharmaceuticals Corporation ("NPC"), Novartis International AG ("Novartis AG") and Novartis International Pharmaceutical, Ltd. ("Novartis International") (collectively "Novartis"), by their undersigned attorneys, bring this action against Defendant, Teva Pharmaceuticals USA, Inc. ("Teva"), for patent infringement and allege as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code. This action relates to Teva's filing Abbreviated New Drug Application ("ANDA") No. 91-192 with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Novartis' ENABLEX® drug product.

The Parties

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

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

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

5. On information and belief, Defendant Teva is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454-1090.

6. On information and belief, Teva is in the business of making and selling generic pharmaceutical products which it distributes in the State of Delaware and throughout the United States.

Jurisdiction and Venue

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

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

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

The Patents in Suit

10. United States Patent No. 5,096,890 ("the '890 Patent"), entitled "Pyrrolidine Derivatives," was duly and lawfully issued on March 17, 1992 to inventors Peter E. Cross and Alexander R. MacKenzie. A copy of the '890 Patent is attached hereto as Exhibit A. Novartis International is the owner by assignment of all rights, title and interest in and to the '890 Patent.

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

The ENABLEX® Drug Product

12. NPC holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for darifenacin 7.5 mg and 15 mg extended release tablets (NDA No. 21-513), which is sold under the trademark ENABLEX®. The claims of the '890 and '864 Patents cover, *inter alia*, ENABLEX® and its method of use.

13. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '890 and '864 Patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to ENABLEX®.

Acts Giving Rise to This Suit

14. Upon information and belief, pursuant to Section 505(j) of the FFDCA (21 U.S.C. § 355(j)), Teva filed ANDA No. 91-192 for darifenacin hydrobromide extended release tablets, seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation of darifenacin hydrobromide extended release tablets 7.5 mg and 15 mg ("Teva's ANDA Products"), before the '890 and '864 Patents expire.

15. Upon information and belief, Teva's ANDA No. 91-192 contained certifications pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV), stating that, in Teva's opinion, the claims of the '890 and '864 Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of Teva's ANDA Products.

16. By letter dated March 19, 2009, Teva sent written notice of its ANDA filing to Novartis. The notice alleges that the claims of the '890 and '864 Patents are invalid, unenforceable, and/or will not be infringed by Teva. Teva's notice also informed Novartis that Teva seeks approval to market Teva's ANDA Products before the '890 and '864 Patents expire.

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

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

Count I: Teva's Infringement the '890 Patent

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

20. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale or importation of Teva's ANDA Products, prior to the expiration of the '890 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

21. Unless enjoined by this Court, Teva, upon FDA approval of Teva's ANDA, will infringe the '890 Patent by making, using, offering to sell, importing and selling Teva's ANDA Products in the United States, and by actively inducing and contributing to infringement by others.

22. Actual commercial manufacture, use, sale or offer for sale of Teva's ANDA Products prior to the expiration of the '890 Patent would constitute infringement of such patent under 35 U.S.C. § 271. ANDA No. 91-192 and Teva's intention to engage in the commercial manufacture, use, sale or offer for sale of Teva's ANDA Products upon receiving FDA approval create an actual case or controversy with respect to infringement of the '890 Patent.

23. Teva had notice of the '890 Patent at the time of its infringement. Teva's infringement has been, and continues to be, willful and deliberate.

24. Plaintiffs will be substantially and irreparably damaged and harmed if Teva's infringement of the '890 Patent is not enjoined.

25. Plaintiffs do not have an adequate remedy at law.

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

Count II: Teva's Infringement the '864 Patent

27. Plaintiffs repeat and reallege the allegations of paragraphs 1-26 as though fully set forth herein.

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

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

30. Actual commercial manufacture, use, sale or offer for sale of Teva's ANDA Products prior to the expiration of the '864 Patent would constitute infringement of such patent under 35 U.S.C. § 271. ANDA No. 91-192 and Teva's intention to engage in the commercial manufacture, use, sale or offer for sale of Teva's ANDA Products upon receiving FDA approval create an actual case or controversy with respect to infringement of the '864 Patent.

31. Teva had notice of the '864 Patent at the time of its infringement. Teva's infringement has been, and continues to be, willful and deliberate.

32. Plaintiffs will be substantially and irreparably damaged and harmed if Teva's infringement of the '864 Patent is not enjoined.

33. Plaintiffs do not have an adequate remedy at law.

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

PRAYER FOR RELIEF

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

(A) A judgment declaring that Defendant Teva has infringed the '890 and '864 Patents by submitting the aforementioned ANDA, and that Defendant's making, using, selling, offering to sell, or importing of Teva's ANDA Products will infringe the '890 and '864 Patents;

(B) A judgment ordering that the effective date of the FDA approval of Defendant's ANDA be a date which is not earlier than the latest of the expiration of the '890 and '864 Patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(C) A judgment permanently enjoining Defendant and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Teva's ANDA Products until after the expiration of the '890 and '864 Patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(D) If Defendant engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Teva's ANDA Products prior to the expiration of the '890 or '864 Patents or any later expiration of exclusivity to which Plaintiffs are or become entitled, a judgment awarding damages to Plaintiffs resulting from such infringement, increased to treble the amount found or assessed, together with interest;

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

(F) Costs and expenses in this action; and

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

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver
Michael P. Kelly (DE ID # 2295)
Andrew S. Dupre (DE ID # 4621)
Daniel M. Silver (DE ID # 4758)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
(302) 984-6300
(302) 984-6399 (fax)
mkelly@mccarter.com
adupre@mccarter.com
dsilver@mccarter.com

OF COUNSEL:
David K. Barr
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
(212) 836-8000

Sylvia M. Becker
KAYE SCHOLER LLP
The McPherson Building
901 Fifteenth St., N.W.
Washington, D.C. 20005
(202) 682-3500

Attorneys for Plaintiffs Novartis Pharmaceuticals Corp, Novartis International AG and Novartis International Pharmaceutical, Ltd.

Dated: April 24, 2009