IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG,

Plaintiffs,

Case No. _____

v.

BRECKENRIDGE PHARMACEUTICAL, INC.,

Defendant.
_____/

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, Novartis Pharmaceuticals Corporation and Novartis AG (collectively "Novartis"), by their attorneys, for their Complaint against Breckenridge Pharmaceutical, Inc. ("Breckenridge") allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, Sections 100 *et seq.* This action relates to an Abbreviated New Drug Application ("ANDA") filed by Breckenridge with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Novartis' Gleevec® drug product.

THE PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07396.

3. Plaintiff Novartis AG ("Novartis AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland.

4. Upon information and belief, Breckenridge Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Florida, having a principal place of business at 6111 Broken Sound Parkway NW, Suite 170, Boca Raton, FL 33487.

JURISDICTION AND VENUE

5. This action for patent infringement arises under 35 U.S.C. § 271.

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

7. Upon information and belief, Breckenridge is in the business of developing and manufacturing generic pharmaceutical products.

8. Upon information and belief, this Court has personal jurisdiction over Breckenridge because Breckenridge is incorporated and exists under the laws of the State of Florida, and because Breckenridge has a principal place of business at 6111 Broken Sound Parkway NW, Suite 170, Boca Raton, FL 33487. Upon information and belief, moreover, Breckenridge markets, distributes and/or sells generic pharmaceutical products within and throughout the United States and within the State of Florida, and for all of these reasons purposefully avails itself of the privilege of conducting business within the State of Florida and throughout this judicial district on a continuous and systematic basis.

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

THE PATENTS IN SUIT

10. United States Patent No. 6,894,051 (the "'051 Patent") duly and legally issued on May 17, 2005 to inventors Jürg Zimmermann, *et al.* A true and correct copy of the '051 Patent is attached hereto as Exhibit A.

11. The '051 Patent is assigned to Novartis AG, and NPC is an exclusive licensee under the '051 Patent.

12. United States Reissue Patent No. RE43,932 (the "RE932 Patent") duly and legally issued on January 15, 2013 to inventors Jürg Zimmermann, *et al.* A true and correct copy of the RE932 Patent is attached hereto as Exhibit B.

13. The RE932 Patent is assigned to Novartis AG, and NPC is an exclusive licensee under the RE932 Patent.

ACTS GIVING RISE TO THIS ACTION

14. Plaintiff NPC holds an approved New Drug Application ("NDA") No. 21588 for Gleevec® tablets containing 100 mg and 400 mg imatinib mesylate, which was approved by the FDA on April 18, 2003.

15. By letter dated June 13, 2014 ("Breckenridge's Notice Letter"), Breckenridge notified Novartis that it had submitted ANDA No. 205990 to the FDA under Section 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, offer to sell or sale of tablets containing 100 mg and 400 mg of imatinib mesylate (the "Imatinib Mesylate ANDA Tablets"). Upon information and belief, Breckenridge stated in its ANDA that its Imatinib Mesylate ANDA Tablets are bioequivalent to Novartis' 100 mg and 400 mg imatinib mesylate Gleevec® tablets.

16. As stated in its Notice Letter, Breckenridge's ANDA was submitted to obtain FDA approval to engage in the commercial manufacture, use, offer to sell or sale of Breckenridge's Imatinib Mesylate ANDA Tablets prior to the expiration of the '051 Patent and the RE932 Patent, which are listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (the "Orange Book") as being applicable to Novartis' Gleevec® tablets. On information and belief, Breckenridge intends to engage in the commercial manufacture, use, offer to sell, sale or importation of its ANDA Imatinib Mesylate Tablets promptly upon receiving FDA approval to do so.

17. In its Notice Letter, Breckenridge notified Novartis that its ANDA contained a "paragraph IV certification" that in Breckenridge's opinion, the '051 Patent and the RE932 Patent are invalid, unenforceable or will not be infringed by the manufacture, use, offer to sell or sale of Breckenridge's Imatinib Mesylate ANDA Tablets.

18. Breckenridge's filing of its ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, sale or importation of its Imatinib Mesylate ANDA Tablets, prior to the expiration of the '051 Patent and the RE932 Patent, constitutes infringement of one or more of the claims of those patents under 35 U.S.C. § 271(e)(2).

19. Breckenridge's commercial manufacture, use, offer to sell, sale or importation of its Imatinib Mesylate ANDA Tablets, prior to the expiration of the '051 Patent and the RE932 Patent, would constitute infringement of the '051 Patent and the RE932 Patent under 35 U.S.C. § 271.

20. Upon FDA approval of Breckenridge's ANDA, Breckenridge will infringe the '051 Patent and the RE932 Patent by making, using, offering to sell, selling or importing its Imatinib Mesylate ANDA Tablets in the United States unless enjoined by this Court.

21. Breckenridge had notice of the '051 Patent and the RE932 Patent at the time of its infringement.

22. Novartis will be substantially and irreparably damaged and harmed if Breckenridge's infringement is not enjoined. Novartis does not have an adequate remedy at law.

WHEREFORE, Novartis respectfully requests the following relief:

(a) a judgment and decree that the '051 Patent and the RE932 Patent are valid and enforceable;

(b) a judgment and decree that Breckenridge has infringed one or more claims of the '051 Patent and the RE932 Patent in violation of 35 U.S.C. § 271;

(c) a judgment declaring that Breckenridge's making, using, offering to sell, selling or importing its Imatinib Mesylate ANDA Tablets will infringe the '051 Patent and the RE932 Patent;

(d) a judgment providing that the effective date of any FDA approval for Breckenridge to make, use, offer to sell, sell or import its Imatinib Mesylate ANDA Tablets be no earlier than the date on which last-expiring patent of the '051 Patent and the RE932 Patent expires, including any associated regulatory exclusivities;

(e) a judgment permanently enjoining Breckenridge from making, using, selling, offering to sell or importing its Imatinib Mesylate ANDA Tablets until after expiration of the '051 Patent and the RE932 Patent, including any associated regulatory exclusivities;

(f) if Breckenridge engages in the commercial manufacture, use, offer to sell, sale or importation of its Imatinib Mesylate ANDA Tablets prior to the expiration of the '051 Patent and the RE932 Patent, a judgment awarding Novartis damages resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(g) a judgment awarding Novartis attorneys' fees in this action pursuant to 35 U.S.C. § 285;

(h) a judgment awarding Novartis costs and expenses in this action; and

(i) a judgment awarding Novartis such further and other relief as this Court may deem just and proper.

Dated: July 28, 2014

Respectfully submitted,

MANUEL KUSHNER
Florida Bar No. 330957
Attorney for the Plaintiffs
KAYE SCHOLER LLP
777 South Flagler Drive, Suite 900 West
West Palm Beach, FL 33401
Primary: manuel.kushner@kayescholer.com
Secondary:Florida-service@kayescholer.com
Telephone: (561) 802-3230
Facsimile: (561) 802-3217

David K. Barr (*pro hac vice* anticipated)
Tatiana N. Alyonycheva (*pro hac vice* anticipated)
Katherine O'Brien (*pro hac vice* anticipated)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
(212) 836-7560

Sylvia M. Becker (*pro hac vice* anticipated)
KAYE SCHOLER LLP
McPherson Building
901 Fifteenth Street, NW
Washington, DC 20005-2327
(202) 682-3579

Attorneys for Plaintiffs Novartis Pharmaceuticals Corporation and Novartis AG