

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC.,

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS
CORPORATION, NOVARTIS AG,
NOVARTIS PHARMA AG, NOVARTIS
INTERNATIONAL PHARMACEUTICAL
LTD. and LTS LOHMANN THERAPIE-
SYSTEME AG,

Defendants.

C.A. No. _____

COMPLAINT

Par Pharmaceutical, Inc. (“Par”), for its Complaint against Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG, Novartis International Pharmaceutical Ltd. and LTS Lohmann Therapie-Systeme AG (collectively, “Defendants”), alleges as follows:

NATURE OF ACTION

1. Par seeks declaratory judgment of non-infringement and invalidity of U.S. Patent No. 6,316,023 (“the ’023 patent”) pursuant to the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(5)(C)(i), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*

PARTIES

2. Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

3. Upon information and belief, Novartis Pharmaceuticals Corporation 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 07936.

4. Upon information and belief, 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.

5. Upon information and belief, Novartis Pharma 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.

6. Upon information and belief, Novartis International Pharmaceutical Ltd. is a corporation organized and existing under the laws of Bermuda, having an office and place of business at 131 Front Street, Hamilton HM12, Bermuda.

7. Upon information and belief, LTS Lohmann Therapie-Systeme AG is a corporation organized and existing under the laws of Germany, having an office and place of business at Lohmannstraße 2, D-56626 Andernach, Germany.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a), and 2201(a); 21 U.S.C. § 355(j)(5)(C)(i)(II); and 35 U.S.C. § 271(e)(5).

9. This Court has personal jurisdiction over Defendants based on, *inter alia*, Defendants' filing of related lawsuits in this jurisdiction, in *Novartis Pharms. Corp. et al. v. Par Pharm., Inc.*, Case Nos. 11-1077-RGA and 13-1467-RGA (D. Del.).

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)-(d), 1400(b), and Defendants' choice of forum.

FACTUAL BACKGROUND

11. U.S. Patent No. 6,316,023 ("the '023 patent") entitled "TTS containing an antioxidant," issued on November 13, 2001. A copy of the '023 patent is attached hereto as Exhibit A.

12. On information and belief, Novartis AG and LTS Lohmann Therapie-Systeme AG are the assignees of the '023 patent.

13. On information and belief, Novartis Pharmaceuticals Corporation is the holder of New Drug Application No. 022083 ("NDA 022083") for rivastigmine transdermal extended release film, 4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr, marketed under the brand name Exelon[®] Patch. In connection with NDA 022083, Novartis Pharmaceuticals Corporation caused the U.S. Food and Drug Administration ("FDA") to list U.S. Patent No. 6,335,031 ("the '031 patent") and the '023 patent in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book").

14. Par submitted to the FDA an Abbreviated New Drug Application ("ANDA") requesting regulatory approval to engage in the commercial manufacture, use, or sale of rivastigmine transdermal extended release film, 13.3 mg/24 hr ("Par's Rivastigmine Product") before the expiration of the Orange Book patents listed for Exelon[®] Patch. Par made certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certifications") that

the '031 and '023 patents listed in the Orange Book for Exelon[®] Patch are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Par's Rivastigmine Product.

15. Par has made substantial preparations for the commercial manufacture, use, and sale of Par's Rivastigmine Product.

16. Defendants have previously asserted the '031 patent against Par in connection with Par's filing of ANDA No. 202339 for its 13.3 mg/24 hr dosage strength rivastigmine transdermal product. *Novartis Pharms. Corp., et al. v. Par Pharm., Inc.*, Case No. 13-1467-RGA (D. Del.).

17. Defendants have previously asserted the '031 and '023 patents against Par in connection with Par's filing of ANDA No. 202339 for its 4.6 mg/24 hr and 9.5 mg/24 hr dosage strength rivastigmine transdermal products. *Novartis Pharms. Corp., et al. v. Par Pharm., Inc.*, Case No. 11-1077-RGA (D. Del.).

18. Defendants have also asserted the '031 and '023 patents against another ANDA filer, Watson Laboratories, Inc., Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.), and Actavis, Inc. (f/k/a Watson Pharmaceuticals, Inc.) (collectively, "Actavis"), in connection with Actavis' ANDA seeking approval to market a rivastigmine transdermal product, in *Novartis Pharms. Corp., et al. v. Watson Labs., Inc., et al.*, Case Nos. 11-1112-RGA (D. Del.) and 13-371-RGA (D. Del.).

19. Defendants have further asserted the '031 and '023 patents against additional ANDA filers, in connection with ANDAs seeking approval to market rivastigmine transdermal products, in *Novartis Pharms. Corp. et al. v. Alvogen Pine Brook Inc., et al.*, Case No. 13-52-

RGA (D. Del.), and *Novartis Pharms. Corp. et al. v. Noven Pharm. Inc.*, Case Nos.13-527 and 14-111-RGA (D. Del.).

20. By listing the '031 and '023 patents in the Orange Book, and previously suing Par and other ANDA filers for alleged infringement of the '031 and '023 patents, Defendants' actions inject uncertainty into the pursuit of regulatory approval and subsequent commercialization of Par's Rivastigmine Product.

21. In response to Par's ANDA filing and Paragraph IV certifications against the '031 and '023 patents, Defendants filed an infringement action selectively asserting only the '031 patent, thus gaining the exclusionary benefit of an automatic 30-month stay of approval of Par's ANDA while jeopardizing only the '031 patent in litigation.

22. Defendants did not assert the '023 patent against Par for its 13.3 mg/24 hr dosage strength rivastigmine product within the statutory 45-day period following Defendants' receipt of Par's Notice Letter.

23. 35 U.S.C. § 271(e)(5) provides that the Court shall have subject matter jurisdiction under 28 U.S.C. § 2201 for a declaratory judgment claim that an Orange Book-listed patent that is not asserted during the statutory 45-day period is invalid and/or not infringed.

24. Should Par prevail in the previously-filed litigation in which only the '031 patent was asserted by Defendants, Par would still be faced with the threat of litigation from Defendants over the '023 patent, relating to Par's Rivastigmine Product.

25. A judgment that Par's Rivastigmine Product will not infringe the '023 patent and/or that the patent is invalid will remove any independent barriers to competition that may exist by virtue of Defendants' maintenance of the listing of the patents in the Orange Book in connection with NDA 022083 for Exelon[®] Patch.

26. Upon information and belief, the first-filer for a 13.3 mg/24 hr rivastigmine transdermal system, generic to Exelon[®] Patch, has not forfeited its 180-day exclusivity under 21 U.S.C. § 355(j)(5)(D).

27. Defendants' actions have resulted in a substantial controversy regarding the '023 patent between Par and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that the '023 patent is invalid and not infringed.

COUNT ONE

Declaratory Judgment Regarding U.S. Patent No. 6,316,023

28. The claims of the '023 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code § 112.

29. The filing of Par's ANDA on Par's Rivastigmine Product did not infringe any valid claim of the '023 patent.

30. The commercial manufacture, use, offer for sale, sale, or importation of Par's Rivastigmine Product would not infringe any valid claim of the '023 patent.

31. An actual and justiciable controversy exists between the parties with respect to the '023 patent, and Par is entitled to a declaratory judgment that the '023 patent is invalid and not infringed by Par.

PRAYER FOR RELIEF

WHEREFORE, Par respectfully requests that this Court enter judgment in its favor and against Defendants and grant the following relief:

- A. Declare that the claims of the '023 patent are invalid;
- B. Declare that the filing of Par's ANDA on Par's Rivastigmine Product did not infringe any claim of the '023 patent;

- C. Declare that the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Par's Rivastigmine Product would not infringe any valid claim of the '023 patent;
- D. Award Par its costs and reasonable attorney fees to the extent permitted by law;
- and
- E. Award Par such other and further relief as the Court deems just and proper.

Of Counsel:

Daniel G. Brown
LATHAM & WATKINS LLP
885 Third Avenue
New York, NY 10022
(212) 906-1200

Roger J. Chin
LATHAM & WATKINS LLP
505 Montgomery Street
Suite 2000
San Francisco, CA 94111
(415) 906-1200

Jennifer Koh
LATHAM & WATKINS LLP
12670 High Bluff Drive
San Diego, CA 92130
(858) 523-5400

Dated: June 27, 2014

/s/ Steven J. Fineman

Steven J. Fineman (#4025)
Katharine C. Lester (#5629)
RICHARDS LAYTON & FINGER, P.A.
One Rodney Square
920 North King Street
Wilmington, DE 19801
(302) 651-7700
Fineman@rlf.com
Lester@rlf.com

*Attorneys for Plaintiff Par Pharmaceutical,
Inc.*