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.*

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).

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

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-

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.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.