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Of Counsel for Plaintiff Horizon Therapeutics, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HORIZON THERAPEUTICS, INC.,

Plaintiff,

v.

PAR PHARMACEUTICAL, INC.,

Defendant.

Civil Action No. 1:16-cv-_____

COMPLAINT

Plaintiff Horizon Therapeutics, Inc., by its undersigned attorneys, brings this action against Defendant Par Pharmaceutical, Inc. ("Defendant" or "Par"), and hereby 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, arising from Defendant's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Plaintiff's pharmaceutical product RAVICTI® (glycerol phenylbutyrate) ("RAVICTI®") prior to the expiration of United States Patent Nos. 9,095,559 ("the '559 patent"), 9,254,278 ("the '278 patent"), and 9,326,966 ("the

THE PARTIES

2. Plaintiff Horizon Therapeutics, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 150 S. Saunders Road, Lake Forest, IL 60045.

3. On information and belief, Defendant Par Pharmaceutical, Inc., is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 6 Ram Ridge Rd, Chestnut Ridge, NY 10977.

4. On information and belief, Par is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this judicial district, through its own actions.

5. On information and belief, Par is registered to do business in the State of New Jersey under Business ID Number 0100071541 and is registered as a manufacturer and wholesale distributor of drugs in the State of New Jersey under Registration Number 5004032.

6. Par has filed Abbreviated New Drug Application ("ANDA") No. 205742 ("the Par ANDA") with the Food and Drug Administration ("FDA") seeking approval to market and sell a generic version of RAVICTI® (glycerol phenylbutyrate oral liquid) ("the Par Product") throughout the United States, including in New Jersey.

7. On information and belief, Par has availed itself of the rights, benefits and privileges of this Court by filing at least one complaint for patent infringement in the District of New Jersey: *Par Pharmaceutical, Inc. and Par Sterile Products, LLC v. Luitpold Pharmaceuticals, Inc., Daiichi Sankyo, Inc. and Daiichi Sankyo Co., Ltd.*, Civil Action No. 2:16-cv-02290.

8. On information and belief, Par has admitted to, consented to or has not contested, the jurisdiction of this Court in at least one prior District of New Jersey action: *Merck Sharp & Dohme Corp. v. Par Sterile Products, LLC, Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., and Par Pharmaceutical Holdings, Inc.*, Civil Action No. 3:16-cv-00948; *Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited v. Par Pharmaceutical, Inc.*, Civil Action No. 2:15-cv-07580; and *Alcon Pharmaceuticals, Ltd., Alcon Laboratories, Inc., and Alcon Research, Ltd. v. Par Pharmaceutical, Inc.*, 3:15-cv-07240.

9. On information and belief, Par has availed itself of the rights, benefits and privileges of this Court by asserting counterclaims in at least three prior District of New Jersey actions: *Merck Sharp & Dohme Corp. v. Par Sterile Products, LLC, Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., and Par Pharmaceutical Holdings, Inc.*, Civil Action No. 3:16-cv-00948; *Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited v. Par Pharmaceutical, Inc.*, Civil Action No. 2:15-cv-07580; and *Alcon Pharmaceuticals, Ltd., Alcon Laboratories, Inc., and Alcon Research, Ltd. v. Par Pharmaceutical, Inc.*, 3:15-cv-07240.

JURISDICTION AND VENUE

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

11. This Court has personal jurisdiction over Defendant by virtue of, *inter alia*, its presence in New Jersey, having conducted business in New Jersey, having availed itself of the rights and benefits of New Jersey law such that it should reasonably anticipate being haled into court in this judicial district, previously submitting to personal jurisdiction in this Court, availing itself of the jurisdiction of this Court (*e.g.*, by the assertion of claims and counterclaims), and having engaged in systematic and continuous contacts with the State of New Jersey through the

marketing and sales of generic drugs throughout the United States, and in particular within this judicial district, through the receipt of revenue from the sales and marketing of generic drug products, including Par products, within this judicial district.

12. This Court also has personal jurisdiction over Defendant by virtue of, *inter alia*, Par's filing of ANDA No. 205742 with the FDA seeking approval to market and sell Par's Product throughout the United States, including to residents of New Jersey and Par's intent to market and sell the Par product, if approved, to residents of this judicial districts.

13. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PATENTS-IN-SUIT

14. On August 4, 2015, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '559 patent entitled "Methods of Therapeutic Monitoring of Nitrogen Scavenging Drugs." At the time of its issue, the '559 patent was assigned to Horizon Therapeutics, Inc. Horizon Therapeutics, Inc. currently is the sole assignee and owner of all right, title and interest in and to the '559 patent, which claims methods related to the treatment of urea cycle disorder patients with glyceryl tri-[4-phenylbutyrate] based on measurement of fasting plasma ammonia levels. A true and correct copy of the '559 patent is attached hereto as Exhibit A.

15. On February 9, 2016, the USPTO duly and legally issued the '278 patent entitled "Methods of Therapeutic Monitoring of Nitrogen Scavenging Drugs." At the time of its issue, the '278 patent was assigned to Horizon Therapeutics, Inc. Horizon Therapeutics, Inc. currently is the sole assignee and owner of all right, title and interest in and to the '278 patent, which claims methods related to the treatment of urea cycle disorder patients with glyceryl tri-[4-

phenylbutyrate] based on measurement of fasting plasma ammonia levels. A true and correct copy of the '278 patent is attached hereto as Exhibit B.

16. On May 3, 2016, the USPTO duly and legally issued the '966 patent entitled "Methods of Therapeutic Monitoring of Nitrogen Scavenging Drugs." At the time of its issue, the '966 patent was assigned to Horizon Therapeutics, Inc. Horizon Therapeutics, Inc. currently is the sole assignee and owner of all right, title and interest in and to the '966 patent, which claims methods related to the treatment of urea cycle disorder patients with glyceryl tri-[4-phenylbutyrate] based on measurement of fasting plasma ammonia levels. A true and correct copy of the '966 patent is attached hereto as Exhibit C.

RAVICTI®

17. Horizon Therapeutics, Inc. is the owner of FDA-approved New Drug Application No. 203284 ("the RAVICTI® NDA") for glycerol phenylbutyrate oral liquid 1.1gm/ml, which is sold by Horizon Pharma USA, Inc. in the United States under the trademark RAVICTI®.

18. RAVICTI® is currently approved by the FDA for use as a nitrogen-binding agent for chronic management of adult and pediatric patients ≥ 2 years of age with urea cycle disorders that cannot be managed by dietary protein restriction and/or amino acid supplementation alone.

19. Pursuant to 21 U.S.C. § 355, and attendant FDA regulations, the '559 patent, the '278 patent, and the '966 patent are listed in the FDA publication entitled "Approved Drug Products and Therapeutic Equivalence Evaluations," ("the Orange Book") for the RAVICTI® NDA.

20. The '559 patent, the '278 patent, and the '966 patent qualify for listing in the Orange Book in connection with NDA No. 203284 because each patent claims an approved use of RAVICTI®.

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