IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

HYPERION THERAPEUTICS, INC., Plaintiff, v. PAR PHARMACEUTICAL, INC., Defendant.	Civ. Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Hyperion Therapeutics (Hyperion) by its attorneys, for its complaint against Par Pharmaceutical, Inc., ("Par" or "Defendant"), alleges as follows:

THE PARTIES

1. Plaintiff Hyperion Therapeutics is a corporation organized and existing under the laws of California and has its principal place of business at 2000 Sierra Point Pkwy, 4th floor; Brisbane, CA 94005.

2. Hyperion is a commercial-stage biopharmaceutical company currently focused on developing treatments for orphan and hepatic diseases. Hyperion does business throughout the United States, including in the State of Texas. Hyperion markets and sells pharmaceutical products to customers in the State of Texas including in this judicial district, and generates substantial revenue from these sales.

3. Upon 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 1 Ram Ridge Rd, Spring Valley, NY 10977.

JURISDICTION AND VENUE

4. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent Nos. 8,404,215 ("the '215 patent") and 8,642,012 ("the '012 patent") (collectively "the patents-in-suit"). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. Defendant is subject to personal jurisdiction in this judicial district by virtue of its, *inter alia*, having conducted business in the State of Texas, and having engaged in substantial, continuous, and systematic contacts with the State through the marketing and selling of pharmaceutical products to customers in the State of Texas. In addition, Defendant is subject to personal jurisdiction in this judicial district because, on information and belief, Defendant will sell, offer to sell, or use its generic product (as defined below in paragraph 20) in the State of Texas and this judicial district, or will have others do so on its behalf.

6. Upon information and belief, Par maintains a website, www.parpharm.com, which states that Par's "sales place it among the top 5 largest generic pharmaceutical companies in the United States." (www.parpharm.com/) (follow "Corporate Information" hyperlink). Par's website further states that "[e]very week in America, more than one million Par prescriptions are dispensed." *Id.* Par's website also states that it has "strong distribution relationships in place at top US retail chains, wholesalers, distributors, managed care organizations, mail order pharmacies and group purchasing organizations."

(www.parpharm.com) (follow "About Us" hyperlink). Par's website is accessible in the State of Texas, including within this judicial district.

7. Upon information and belief, many of the authorized distributors with which Par has strong relationships are companies operating in the state of Texas, such as Walgreens, CVS Pharmacy, and Wal-Mart. On information and belief, Par offers generic pharmaceutical products – including generic versions of Accupril, Dostinex, Flonase, Paxil, and Prozac – for sale at these distributors, and Defendant derives significant revenue from these sales within the State of Texas, including within this judicial district. (www.parpharm.com) (follow "Out Products" hyperlink).

8. Upon information and belief, Defendant engages in ongoing business relationships with businesses organized and existing under the laws of the State of Texas and/or with a principal place of business in the State.

9. Upon information and belief, Defendant will use its existing pharmacy relationships to distribute its proposed generic product (as defined below in paragraph 20) throughout the United States, including in the State of Texas and in this judicial district. Accordingly, that generic product will be offered for sale, sold, and used in the State of Texas including in this judicial district.

10. Further, upon information and belief, Par Pharmaceutical, Inc. has purposefully availed itself of the benefits and protections of this judicial district when litigating patent disputes. Defendant has subjected itself to the jurisdiction of this Court and asserted counterclaims in civil actions in the state of Texas in at least the following cases: *Pozen Inc. v. Par Pharmaceutical, Inc.*, Case No. 6:08-cv-00437-LED (E.D. Tex.); *Galderma Laboratories L.P. et. al., v. Par Pharmaceutical, Inc.*, Case No. 3:12-cv-02563-K (N.D. Tex.).

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

REGULATORY REQUIREMENTS FOR APPROVAL OF NEW AND GENERIC DRUGS

12. Any person wishing to market a pioneering drug – that is, a new drug that has not previously been approved by FDA – must first file a New Drug Application ("NDA") with FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b). To secure approval of an NDA, the NDA applicant must, among other things, collect and submit to FDA extensive animal and human clinical trial data at a substantial cost of time and money.

13. A person wishing to market a generic copy of a pioneering drug that previously has been approved by FDA may follow a truncated approval process by filing an ANDA for a generic version of the drug. In the ANDA, the applicant must demonstrate, among other things, bioequivalence of the generic copy of the pioneering drug. 21 U.S.C. § 355(j)(2)(A)(iv).

14. However, unlike an NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. The ANDA applicant is not required, for example, to conduct well-controlled clinical trials concerning the safety and effectiveness of the proposed drug. Instead, the ANDA applicant is permitted to piggy-back on the safety and effectiveness data developed and submitted by the approved NDA holder. 21 U.S.C. § 355(j).

15. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of use that previously have been approved in connection with an approved NDA. 21 U.S.C. § 355(j)(2)(A)(i).

16. No person may market in the United States a new drug without an approved NDA or a generic version of a drug without an approved ANDA. 21 U.S.C. § 355(a).

HYPERION'S APPROVED DRUG PRODUCT

17. Hyperion is the holder of an approved new drug application, NDA No. 20-3284, for a glycerol phenylbutyrate oral liquid, 1.1gm/ml. The NDA was first approved by FDA on February 1, 2013, and Hyperion markets the approved drug product under the tradename RAVICTI®. RAVICTI® is approved 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.

18. FDA has listed the '215 and '012 patents in the Orange Book – formally known as Approved Drug Products With Therapeutic Equivalence Evaluations – in connection with NDA No. 20-3284. Additionally, FDA has listed United States Patent No. 5,968,979 ("the '979 patent"), in connection with NDA No. 20-3284.

19. The '215, '012, and '979 patents qualify for listing in the Orange Book in connection with NDA No. 20-3284 because each individually claims the approved drug product and an approved use of the drug product that is the subject of that NDA.

ANDA NO. 20-5742

20. Upon information and belief, Par submitted to FDA an ANDA (ANDA No. 20-5742), a paragraph III certification under section 505(j)(2)(A)(vii)(III) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(III), and a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for a glycerol phenylbutyrate oral liquid, 1.1gm/ml purportedly bioequivalent to RAVICTI® (the "generic product"). The purpose of the ANDA, paragraph III certification and paragraph IV

certification is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the generic product.

21. Upon information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 20-5742 for the generic product is 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, i.e., the same indication as that set forth in the approved labeling for RAVICTI®.

22. Upon information and belief, Par sent Plaintiff a "Notice of Paragraph IV Certification" dated March 12, 2014 (the "Notice Letter"). The Notice Letter represented that Par had submitted to FDA ANDA No. 20-5742 and purported paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for glycerol phenylbutyrate oral liquid, 1.1 gm/ml that is purportedly bioequivalent to Hyperion's RAVICTI® oral liquid. Additionally, as part of its submission of ANDA No. 20-5742 to FDA, Par submitted a purported paragraph III certification under section 505(j)(2)(A)(vii)(III) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(III) for the '979 patent.

23. Upon information and belief, the purpose of the ANDA and purported paragraph III and paragraph IV certifications was to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of Hyperion's glycerol phenylbutyrate oral liquid before the expiration of the patents listed in the Orange Book for NDA No. 20-3284. Hence, Par's purpose in submitting the ANDA is to market products described therein before expiration of the '215 and '012 patents.

COUNT I:
INFRINGEMENT OF THE ’215 PATENT UNDER 35 U.S.C. § 271(e)

24. Plaintiff re-alleges paragraphs 1 through 23 above as if fully set forth herein.

25. On March 26, 2013, the United States Patent and Trademark Office duly and legally issued the ’215 patent, entitled “Methods of Therapeutic Monitoring of Nitrogen Scavenging.” The term of the ’215 patent runs through March 9, 2032. A true and correct copy of the ’215 patent is attached hereto as Exhibit A.

26. Hyperion is the owner of the ’215 patent, having acquired the entire right, title, and interest in the ’215 patent through an assignment from the inventors.

27. The use of RAVICTI® is covered by the claims of the ’215 patent.

28. As owner of the ’215 patent, Hyperion has the right to enforce the ’215 patent.

29. The generic glycerol phenylbutyrate oral liquid product for which Defendant seeks approval in ANDA No. 20-5742 falls within one or more of the claims of the ’215 patent. If approved, the importation, manufacture, sale, offer for sale or use of the generic glycerol phenylbutyrate oral liquid product that is the subject of ANDA No. 20-5742 would infringe one or more of the claims of the ’215 patent.

30. The conditions of use for the generic glycerol phenylbutyrate oral liquid product for which Defendant seeks approval in ANDA No. 20-5742 fall within one or more of the claims of the ’215 patent. If approved, use of the generic glycerol phenylbutyrate oral liquid product in accordance with the proposed labeling submitted in ANDA No. 20-5742 would infringe one or more of the claims of the ’215 patent.

31. Defendant is liable for infringement of the ’215 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of filing ANDA No. 20-5742 with a paragraph IV certification seeking FDA approval of ANDA No. 20-5742.

COUNT II:
INFRINGEMENT OF THE ’012 PATENT UNDER 35 U.S.C. § 271(e)

32. Plaintiff re-alleges paragraphs 1 through 31 above as if fully set forth herein.

33. On February 4, 2014, the United States Patent and Trademark Office duly and legally issued the ’012 patent, entitled “Methods of Treatment Using Ammonia-Scavenging Drugs.” The term of the ’012 patent runs through September 22, 2030. A true and correct copy of the ’012 patent is attached hereto as Exhibit B.

34. Hyperion is the owner of the ’012 patent, having acquired the entire right, title, and interest in the ’012 patent through an assignment from the inventors.

35. The use of RAVICTI® is covered by the claims of the ’012 patent.

36. As owner of the ’012 patent, Hyperion is authorized to enforce the ’012 patent.

37. The generic glycerol phenylbutyrate oral liquid product for which Defendant seeks approval in ANDA No. 20-5742 falls within one or more of the claims of the ’ ’012 patent. If approved, the importation, manufacture, sale, offer for sale or use of the generic glycerol phenylbutyrate oral liquid product that is the subject of ANDA No. 20-5742 would infringe one or more of the claims of the ’ 012 patent.

38. The conditions of use for the generic glycerol phenylbutyrate oral liquid product for which Defendant seeks approval in ANDA No. 20-5742 fall within one or more of the claims of the ’ 012 patent. If approved, use of the generic glycerol phenylbutyrate oral liquid

product in accordance with the proposed labeling submitted in ANDA No. 20-5742 would infringe one or more of the claims of the ’ 012 patent.

39. Defendant is liable for infringement of the ’ 012 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of filing ANDA No. 20-5742 with a paragraph IV certification seeking FDA approval of ANDA No. 20-5742.

COUNT III:
INFRINGEMENT OF ’215 PATENT UNDER 35 U.S.C. §§ 271(a), (b) & (c)
AGAINST DEFENDANT

40. Plaintiff re-alleges paragraphs 1 through 39 above as if fully set forth herein.

41. Upon information and belief, if ANDA No. 20-5742 is approved, Defendant intends to manufacture, use, offer for sale, and sell in the United States, and import into the United States, the generic glycerol phenylbutyrate oral liquid product for which approval is sought in ANDA No. 20-5742.

42. The importation, manufacture, sale, offer for sale or use in the United States of the generic glycerol phenylbutyrate oral liquid product proposed and intended by Defendant would infringe one or more claims of the ’215 patent, and Defendant would be liable for direct infringement under 35 U.S.C. § 271(a).

43. Upon information and belief, if approved, the generic glycerol phenylbutyrate oral liquid product for which approval is sought in Defendant’s ANDA No. 20-5742 will be administered to human patients for the use as a nitrogen-binding agent for chronic management of adult and pediatric patients $\geq$ 2 years of age with urea cycle disorders that cannot be managed by dietary protein restriction and/or amino acid supplementation alone, which administration would constitute direct infringement of one or more claims of the ’215 patent.

Upon information and belief, this infringement will occur at Defendant's behest, with their intent, knowledge, and encouragement, and Defendant will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Hyperion's rights under the '215 patent.

44. Defendant's manufacture, use, offer for sale or sale in the United States, or importation into the United States, of the generic glycerol phenylbutyrate oral liquid product for which approval is sought in ANDA No 20-5742 would actively induce and contribute to infringement of the '215 patent, and Defendant would be liable as infringers under 35 U.S.C. §§ 271(b) and/or (c).

45. Plaintiff will be irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to infringement of the '215 patent. Plaintiff does not have an adequate remedy at law.

COUNT IV:
INFRINGEMENT OF '012 PATENT UNDER 35 U.S.C. §§ 271(a), (b) & (c)
AGAINST DEFENDANT

46. Plaintiff re-alleges paragraphs 1 through 45 above as if fully set forth herein.

47. Upon information and belief, if ANDA No. 20-5742 is approved, Defendant intends to manufacture, use, offer for sale, and sell in the United States, and import into the United States, the generic glycerol phenylbutyrate oral liquid product for which approval is sought in ANDA No. 20-5742.

48. The importation, manufacture, sale, offer for sale or use in the United States of the generic glycerol phenylbutyrate oral liquid product proposed and intended by

Defendant would infringe one or more claims of the ’012 patent, and Defendant would be liable for direct infringement under 35 U.S.C. § 271(a).

49. Upon information and belief, if approved, the generic glycerol phenylbutyrate oral liquid product for which approval is sought in Defendant’s ANDA No. 20-5742 will be administered to human patients for the 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, which administration would constitute direct infringement of one or more claims of the ’012 patent. Upon information and belief, this infringement will occur at Defendant’s behest, with their intent, knowledge, and encouragement, and Defendant will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Hyperion’s rights under the ’012 patent.

50. Defendant’s manufacture, use, offer for sale or sale in the United States, or importation into the United States, of the generic glycerol phenylbutyrate oral liquid product for which approval is sought in ANDA No 20-5742 would actively induce and contribute to infringement of the ’012 patent, and Defendant would be liable as infringers under 35 U.S.C. §§ 271(b) and/or (c).

51. Plaintiff will be irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to infringement of the ’012 patent. Plaintiff does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff seeks the following relief:

A. A judgment that Defendant has infringed the ’215 patent under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that Defendant has infringed the ’012 patent under 35 U.S.C. § 271(e)(2)(A);

C. A judgment and order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of ANDA No.20-5742 for generic glycerol phenylbutyrate oral liquid product be no earlier than the date of expiration of the ’215 patent and ’012 patent and any associated regulatory exclusivities extending that date;

D. A judgment declaring that Defendant’s manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic glycerol phenylbutyrate oral liquid product for which approval is sought in ANDA No. 20-5742 would constitute infringement of the ’215 patent, or would induce or contribute to such infringement, pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

E. A judgment declaring that Defendant’s manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the generic glycerol phenylbutyrate oral liquid product for which approval is sought in ANDA No. 20-5742 would constitute infringement of the ’012 patent, or would induce or contribute to such infringement, pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

F. A permanent injunction enjoining Defendant and its respective officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making, using, selling, or offering to sell in the United States,

or importing into the United States, the generic glycerol phenylbutyrate oral liquid product for which approval is sought in ANDA No. 20-5742, or any glycerol phenylbutyrate oral liquid product that infringes or induces or contributes to the infringement of the ’215 or ’012 patents, until expiration of those patents and associated regulatory exclusivities extending that date;

G. A finding that this is an exceptional case, and an award of attorneys’ fees in this action pursuant to 35 U.S.C. § 285;

H. An award of costs and expenses in this action; and

I. Such further and other relief as this Court determines to be just and proper.

Dated: April 23, 2014.

Respectfully submitted,

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