IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KERYX BIOPHARMACEUTICALS, INC. and PANION & BF BIOTECH, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
PAR PHARMACEUTICAL, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Keryx Biopharmaceuticals, Inc. ("Keryx") and Panion & BF Biotech, Inc. ("Panion") (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendant Par Pharmaceutical, Inc. ("Par"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, et seq., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, arising from Par's submission of Abbreviated New Drug Application ("ANDA") No. 208217 ("Par's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Keryx's AURYXIA® (Ferric Citrate) Tablets ("Par's Proposed Product") prior to the expiration of United States Patent Nos. 8,093,423 (the "'423 patent") and 9,387,191 (the "'191 patent") (the "patents-in-suit") owned by Plaintiffs.

THE PARTIES

2. Plaintiff Keryx is a corporation organized and existing under the laws of Delaware with a principal place of business at One Marina Park Drive, Twelfth Floor, Boston, Massachusetts 02210.

3. Plaintiff Panion is a corporation organized and existing under the laws of Taiwan, with its principal place of business at 16F No. 3, Yuanqu Street, Nangang District, Taipei, Taiwan.

4. On information and belief, Par Pharmaceutical is a corporation organized and existing under the laws of New York, having its principal place of business at One Ram Ridge Road, Chestnut Ridge, NY 10977.

THE PATENTS-IN-SUIT

5. On January 10, 2012, the USPTO duly and lawfully issued the '423 patent, entitled, "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Method of Making Same." The '423 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '423 patent that are relevant to this litigation. A copy of the '423 patent is attached hereto as Exhibit A.

6. On July 12, 2016, the USPTO duly and lawfully issued the '191 patent, entitled, "Ferric Citrate Dosage Forms." The '191 patent is assigned to Keryx. A copy of the '191 patent is attached hereto as Exhibit B.

THE AURYXIA® (FERRIC CITRATE) DRUG PRODUCT

7. Keryx holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for ferric citrate, 210 mg tablets (NDA No. 205874), which it sells under the trade name AURYXIA®. AURYXIA® is an orally available, absorbable, iron-based medicine. AURYXIA® is FDA-approved for the control of serum phosphorus levels in adult patients with chronic kidney disease on dialysis, and for the treatment of iron deficiency anemia in adult patients with chronic kidney disease not on dialysis. The claims of the patents-in-suit cover, among other things, novel forms of ferric citrate, methods of controlling phosphate retention, methods of decreasing serum calcium levels, and methods of treating hyperphosphatemia.

8. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to AURYXIA®.

JURISDICTION AND VENUE

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

10. On information and belief, Par has submitted, or caused to be submitted to the FDA, Par's ANDA. On information and belief, upon FDA approval of Par's ANDA, Par intends to commercially manufacture, import, market, offer for sale, and/or sell Par's Proposed Product throughout the United States including in this district.

11. This Court has personal jurisdiction over Par because of, among other things, its systematic and continuous contacts with the State of Delaware. On information and belief, Par regularly and continuously transacts business within Delaware, including by importing, marketing and/or selling pharmaceutical products in Delaware. On information and belief, Par derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware. On information and belief, Par derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district.

12. On May 21, 2019, Par's counsel communicated to Plaintiffs' counsel that Par consented to jurisdiction in this judicial district for purposes of this action.

13. On information and belief, Par has been sued previously in this District and has not challenged personal jurisdiction. *See, e.g.*, *Merck Sharp & Dohme Corp. v. Anchen Pharms., Inc.*, C.A. No. 19-311 (D. Del.); *Novartis Pharms. Corp. v. Accord Healthcare Inc.*, C.A. No. 18-1043

(D. Del.); *Novartis Pharms. Corp. v. Par Pharm. Inc.*, C.A. No. 15-78 (D. Del.); *Novartis Pharms. Corp. v. Par Pharm. Inc.*, C.A. No. 14-1494 (D. Del.); *Novartis Pharms. Corp. v. Par Pharm. Inc.*, C.A. No. 14-1289 (D. Del.).

14. Par has further availed itself of the jurisdiction of this Court by previously initiating litigation in this District. *See, e.g.*, *Par Pharm. Inc. v. Amphastar Pharms., Inc.*, C.A. No. 18-2032 (D. Del.); *Par Pharm. Inc. v Hospira, Inc.*, C.A. No. 17-944 (D. Del.); *Par Pharm. Inc. v. Amneal Pharms Co. GmbH*, C.A. No. 19-712 (D. Del.); *Par Pharm. Inc. Breckenridge Pharm. Inc.*, C.A. No. 15-1039 (D. Del.).

15. Venue is proper in this District under 28 U.S.C. §§ 1391 and/or 1400(b), including because, among other things, Par is subject to personal jurisdiction in this judicial district, as set forth above, and has committed acts of infringement and, upon information and belief, will commit further acts of infringement in this District.

16. On May 22, 2019, Par's counsel communicated to Plaintiffs' counsel that Par consented to venue in this judicial district for purposes of this action.

17. On information and belief, Par has been previously sued in this District and has not challenged venue. *See, e.g.*, *Merck Sharp & Dohme Corp. v. Anchen Pharms., Inc.*, C.A. No. 19-311 (D. Del.); *Novartis Pharms. Corp. v. Accord Healthcare Inc.*, C.A. No. 18-1043 (D. Del.); *Novartis Pharms. Corp. v. Par Pharm. Inc.*, C.A. No. 15-78 (D. Del.); *Novartis Pharms. Corp. v. Par Pharm. Inc.*, C.A. No. 14-1494 (D. Del.); *Novartis Pharms. Corp. v. Par Pharm. Inc.*, C.A. No. 14-1289 (D. Del.).

ACTS GIVING RISE TO THIS SUIT

18. Pursuant to Section 505 of the FFDCA, Par submitted Par's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Par's Proposed Product before the patents-in-suit expire.

19. On information and belief, following FDA approval of Par's ANDA, Par will manufacture, use, offer to sell, or sell Par's Proposed Product throughout the United States, or import such generic products into the United States.

20. On information and belief, in connection with the filing of its ANDA as described above, Par provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Par's Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Par's ANDA.

21. By letter dated April 11, 2019, Par sent written notice of its Paragraph IV Certification to Plaintiffs ("Par's Notice Letter"). Par's Notice Letter alleged that the claims of the patents-in-suit will not be infringed by the activities described in Par's ANDA. Par's Notice Letter also informed Plaintiffs that Par seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Par's Proposed Product before the patents-in-suit expire.

22. In Par's Notice Letter, Par purported to offer to provide access to certain confidential information and materials within Par's ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). Par's offer of confidential access was conditioned on terms identified in Par's Notice Letter. The terms and conditions of Par's offer of confidential access were unreasonable and beyond those that would apply under a protective order. The restrictions Par sought to impose on access to its ANDA contravened 21 U.S.C. § 355(j)(5)(C)(i)(III). Plaintiffs

notified Par that its offer of confidential access did not comply with 21 U.S.C. § 355(j)(5)(C)(i)(III) on April 29, 2019. The parties further communicated about the terms of such confidential access but did not reach agreement with sufficient time remaining in the 45-day period to enable Keryx to access and review Par's ANDA. To date, Par has not provided any portion of its ANDA to Plaintiffs.

23. This Complaint is being filed before expiration of the forty-five days from the date Plaintiffs received Par's Notice Letter.

COUNT I
Infringement of the '423 Patent

24. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-23 as if fully set forth herein.

25. Par's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Par's Proposed Product, prior to the expiration of the '423 patent, constitutes infringement of one or more of the claims of the '423 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, such as, for example, claim 7.

26. A justiciable controversy exists between the parties hereto as to the infringement of the '423 patent.

27. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will actively induce infringement of one or more claims of the '423 patent under 35 U.S.C. § 271(b), such as, for example, claim 7, by encouraging others, including but not limited to healthcare providers and patients, to use, offer for sale, sell, or import Par's Proposed Product in the United States. On information and belief, upon FDA approval of Par's ANDA, Par will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers

and patients, with knowledge of the '423 patent and with knowledge that its acts are encouraging infringement.

28. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will contributorily infringe one or more claims of the '423 patent under 35 U.S.C. § 271(c), such as, for example, claim 7, by offering to sell, selling, and/or importing Par's Proposed Product in the United States. Par's Proposed Product is a material for use in practicing methods claims in the '423 patent that constitutes a material part of those claims' inventions. On information and belief, Par knew and knows that Par's Proposed Product is especially made or adapted for use in infringing one or more claims of the '423 patent, and that Par's Proposed Product is not a staple article or commodity with a substantial non-infringing use.

29. Plaintiffs will be substantially and irreparably damaged and harmed if Par's infringement of the '423 patent is not enjoined.

30. Plaintiffs do not have an adequate remedy at law.

31. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II
Infringement of the '191 Patent

32. Plaintiffs repeat and reallege the allegations of the preceding paragraphs 1-23 as if fully set forth herein.

33. Par's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Par's Proposed Product, prior to the expiration of the '191 patent, constitutes infringement of one or more of the claims of the '191 patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, such as, for example, claims 1, 6, 11 and 16.

34. A justiciable controversy exists between the parties hereto as to the infringement of the '191 patent.

35. Unless enjoined by this Court, upon FDA approval of Par's ANDA, Par will infringe one or more claims of the '191 patent under at least 35 U.S.C. § 271(a), such as, for example, claims 1, 6, 11 and 16, by making, using, offering to sell, selling, and/or importing Par's Proposed Product in the United States.

36. Plaintiffs will be substantially and irreparably damaged and harmed if Par's infringement of the '191 patent is not enjoined.

37. Plaintiffs do not have an adequate remedy at law.

38. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Par has infringed the patents-in-suit under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 208217 to the FDA;

B. A Declaratory Judgment under 28 U.S.C. § 2201 that Par's commercial manufacture, use, offer to sell, sale, or importation Par's Proposed Product will infringe one or more claims of the patents-in-suit;

C. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of FDA approval of ANDA No. 208217 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

D. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Par, its officers, agents, attorneys and employees, and those acting in privity or concert

with them, from making, using, offering to sell, selling, or importing Par's Proposed Product, or from directly infringing or actively inducing or contributing to the infringement of claims of the patents-in-suit, until after the expiration of the patents-in-suit or any later expiration of exclusivity to which Plaintiffs are or become entitled;

E. A Declaratory Judgment under 28 U.S.C. § 2201 that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Par's Proposed Product will directly infringe, induce, and/or contribute to infringement of the patents-in-suit;

F. If Par engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Par's Proposed Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

G. A Declaratory Judgment under 28 U.S.C. § 2201 that the patents-in-suit remain valid and enforceable;

H. A Judgment finding that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Plaintiffs their attorneys' fees incurred in this action;

I. A Judgment awarding Plaintiffs their costs and expenses incurred in this action; and

J. Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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