IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC. and FERRING INTERNATIONAL CENTER S.A.,	)	
Plaintiffs,	)	
v.	)	C.A. No.
PAR PHARMACEUTICAL, INC.	)	
Defendant.	)	

COMPLAINT

Plaintiffs Ferring Pharmaceuticals Inc. ("Ferring Pharma") and Ferring International Center S.A. ("FICSA") (collectively, "Ferring") bring this action against Defendant Par Pharmaceutical, Inc. ("Par") and allege as follows:

PARTIES

1. Plaintiff FICSA is a Swiss private limited liability company having its offices at Ch. de la Vergognausaz 50, 1162 Saint-Prex, Switzerland.

2. Plaintiff Ferring Pharma is a private corporation organized under the laws of the State of Delaware, having its principal place of business at 100 Interpace Parkway, Parsippany, New Jersey 07054.

3. On information and belief, Defendant Par is a corporation organized under the laws of the State of Delaware, having its principal place of business at One Ram Ridge Road, Spring Valley, New York 10977.

4. On information and belief, Par is in the business of, *inter alia*, developing, manufacturing, packaging, and obtaining regulatory approval for numerous generic versions of

branded pharmaceutical products for sale and use throughout the United States, including throughout the State of Delaware.

JURISDICTION AND VENUE

5. This action arises under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively.

6. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202 because there is an actual, substantial, and continuing justiciable case or controversy between Ferring and Par regarding the validity, infringement, and enforceability of the patents in suit.

7. This Court has personal jurisdiction over Par at least because Par is a corporation organized and existing under the laws of the State of Delaware, and by virtue of, *inter alia*, Par's having availed itself of the rights and benefits of the laws of the State of Delaware and having engaged in systematic and continuous contacts with the State of Delaware.

8. On information and belief, this Court has personal jurisdiction over Par by virtue of, *inter alia*, Par's marketing and sales activities in this District, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products in this District.

9. On information and belief, Par conducts substantial business in this District, regularly solicits business from, does business with, and derives value from goods and services provided to customers in this District.

10. On information and belief, Par has derived substantial revenue from sales of pharmaceutical products in this District.

11. This Court has personal jurisdiction over Par because Par has purposefully availed itself of the benefits and protections of the State of Delaware's laws such that it should reasonably anticipate being haled into court in this District. Par has previously been sued in this District and has affirmatively availed itself of the jurisdiction of this Court, both by filing suit in this District and by filing counterclaims in this District. (*See, e.g.*, D.I. 13 in *Par Pharmaceutical Inc. v. Breckenridge Pharmaceutical Inc.*, C.A. No. 13-cv-1114-SLR; D.I. 15 in *Reckitt Benckiser Pharmaceuticals Inc. et al. v. Par Pharmaceutical, Inc. et al.*, C.A. No. 14-cv-422-RGA; D.I. 8 in *Reckitt Benckiser Pharmaceuticals Inc. et al. v. Par Pharmaceutical, Inc. et al.*, C.A. No. 14-cv-1573-RGA; D.I. 98 in *Takeda Pharmaceuticals U.S.A., Inc. v. Par Pharmaceutical, Inc. et al.*, C.A. No. 13-cv-1524-SLR.)

12. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400.

13. On information and belief, Par is subject to personal jurisdiction in this District and thus resides in this District under 28 U.S.C. § 1391(b)(1).

NATURE OF THE ACTION

14. This is an action for infringement of United States Patent Numbers 8,450,338 ("the '338 patent") and 8,481,083 ("the '083 patent") (collectively, the "Patents in Suit") under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively. This action involves Ferring's drug product Prepopik®, indicated for cleansing of the colon as a preparation for colonoscopy in adults.

FERRING'S PREPOPIK® NDA

15. Ferring Pharma is the holder of approved New Drug Application ("NDA") No. 202535 for Prepopik® (sodium picosulfate, magnesium oxide and citric acid) for Oral Solution.

16. On July 16, 2012, the United States Food and Drug Administration ("FDA") approved NDA No. 202535 for the manufacture, marketing, and sale of Prepopik® for cleansing

of the colon as a preparation for colonoscopy in adults. Ferring has sold Prepopik® under NDA No. 202535 since its approval.

THE PATENTS IN SUIT

17. On May 28, 2013, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '338 patent, which bears the title "Granular Compositions of Sodium Picosulfate and Potassium Bicarbonate and Uses Thereof" naming Haijun Xu and Tiejun Diao as inventors. A true and correct copy of the '338 patent is attached as Exhibit A.

18. Plaintiff FICSA is the owner by assignment of the '338 patent, and Plaintiff Ferring Pharma is an exclusive licensee of the '338 patent.

19. On July 9, 2013, the USPTO duly and legally issued the '083 patent, which bears the title "Granular Compositions of Magnesium Oxide and Citric Acid and Uses Thereof" naming Haijun Xu and Tiejun Diao as inventors. A true and correct copy of the '083 patent is attached as Exhibit B.

20. Plaintiff FICSA is the owner by assignment of the '083 patent, and Plaintiff Ferring Pharma is an exclusive licensee of the '083 patent.

21. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '338 patent and the '083 patent are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book") as covering Prepopik®.

PAR'S PARAGRAPH IV NOTICE LETTER AND THE CURRENT CONTROVERSY

22. Par sent a letter dated January 9, 2015 to Ferring Pharma and FICSA (the "Notice Letter") notifying Ferring that Par had filed ANDA No. 205743 ("Par's ANDA") seeking approval to commercially manufacture, use, or sell a generic version of Ferring's Prepopik® ("Par's ANDA Product") prior to the expiration of the '338 patent and the '083 patent (*i.e.*, the Patents in Suit). The Notice Letter stated that Par was providing information to Ferring pursuant

to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act ("the FDCA") and 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95. Ferring received the Notice Letter on January 12, 2015.

23. As stated in the Notice Letter, Par's ANDA contains "certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), [indicating] that in Par's opinion, the [Patents in Suit] are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the product for which the application is submitted [*i.e.*, Par's ANDA Product]" ("Paragraph IV Certifications").

24. Attached to the Notice Letter was a purported "Offer of Confidential Access" pursuant to 21 U.S.C. § 355(j)(5)(c)(i)(III) (the "OCA").

25. The OCA offered limited access to certain Par confidential information regarding Par's ANDA Product. Ferring subsequently notified Par that certain terms of the OCA were unreasonable and proposed modifications.

26. On February 18, 2015, Par notified Ferring that Par was unable to agree to Ferring's proposed modifications to Par's OCA. Accordingly, Par has not provided Ferring with a copy of any portion of its ANDA or any information regarding Par's ANDA Product beyond the information that was set forth in Par's Notice Letter.

27. Par attached a "DETAILED STATEMENT OF THE FACTUAL AND LEGAL BASES FOR PAR'S OPINION THAT UNITED STATES PATENT NOS. 8,450,338 AND 8,481,083 ARE INVALID, UNENFORCEABLE, AND/OR WILL NOT BE INFRINGED" to the Notice Letter (the "Detailed Statement"). The Detailed Statement alleged that each and every claim of the Patents in Suit was invalid and that some claims would not be infringed.

28. Ferring commenced this action within forty-five (45) days of receiving the Notice Letter.

29. There is an actual, real, immediate, and justiciable controversy between Ferring and Par regarding the validity and enforceability of the Patents in Suit and whether Par's ANDA Product will infringe the Patents in Suit.

COUNT I

Infringement of the '338 patent

30. Ferring realleges paragraphs 1 to 29 and incorporates them by reference.

31. Par's submission of Par's ANDA to the FDA under § 505(j) of the FDCA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Par's ANDA Product before the expiration of the '338 patent was an act of infringement of the '338 patent under 35 U.S.C. § 271(e)(2).

32. Par's manufacture, use, sale, offer for sale, or importation into the United States of Par's ANDA Product prior to the expiration of the '338 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '338 patent under 35 U.S.C. § 271(a).

33. Ferring is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Par's ANDA No. 205743 be a date that is not earlier than the expiration of the term of the '338 patent, including any extension(s) granted by the USPTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '338 patent to which Ferring is or becomes entitled.

34. There is an actual case or controversy between Ferring and Par regarding whether the process used to make Par's ANDA Product infringes claims 8 to 19 of the '338 patent.

35. Par has made, and will continue to make, substantial preparation to import into the United States and/or to use, offer to sell, and/or sell within the United States Par's ANDA

Product, which is made by a process claimed in one more of claims 8 to 19 of the ’338 patent, prior to the expiration of the ’338 patent.

36. Par’s importation into the United States and/or use, offer to sell, and/or sale of Par’s ANDA Product within the United States will constitute infringement of one or more of claims 8 to 19 of the ’338 patent under 35 U.S.C. § 271(g).

37. Ferring is entitled to a declaratory judgment that Par’s importation into the United States and/or use, offer to sell, and/or sale of Par’s ANDA Product within the United States will constitute infringement of one or more of claims 8 to 19 of the ’338 patent under 35 U.S.C. § 271(g).

38. Ferring will be irreparably harmed by Par’s infringing activities unless those activities are enjoined by this Court. Ferring has no adequate remedy at law.

COUNT II

Infringement of the ’083 patent

39. Ferring realleges paragraphs 1 to 38 and incorporates them by reference.

40. Par’s submission of Par’s ANDA to the FDA under § 505(j) of the FDCA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Par’s ANDA Product before the expiration of the ’083 patent was an act of infringement of the ’083 patent under 35 U.S.C. § 271(e)(2).

41. Par’s manufacture, use, sale, offer for sale, or importation into the United States of Par’s ANDA Product, prior to the expiration of the ’083 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the ’083 patent under 35 U.S.C. § 271(a).

42. Ferring is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Par’s ANDA No. 205743 be a date

that is not earlier than the expiration of the term of the ’083 patent, including any extension(s) granted by the USPTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the ’083 patent to which Ferring is or becomes entitled.

43. Ferring will be irreparably harmed by Par’s infringing activities unless those activities are enjoined by this Court. Ferring has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Ferring respectfully requests the following judgment and relief:

a. A declaration that the claims of United States Patent Number 8,450,338 and United States Patent Number 8,481,083 are valid and enforceable;

b. A declaration that Par’s submission to the FDA of ANDA No. 205743 to obtain approval for the commercial manufacture, use, offer for sale, sale in, or importation into the United States of Par’s ANDA Product before the expiration of United States Patent Number 8,450,338 and United States Patent Number 8,481,083 was an act of infringement under 35 U.S.C. § 271(e)(2)(A);

c. A declaration that Par’s manufacture, use, offer to sell, sale in, and/or importation into the United States of Par’s ANDA Product prior to the expiration of United States Patent Number 8,450,338 and United States Patent Number 8,481,083 will infringe one or more claims of United States Patent Number 8,450,338 and United States Patent Number 8,481,083 under 35 U.S.C. § 271;

d. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283, enjoining Par and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from infringing any claims of United States Patent Number 8,450,338 and United States Patent Number 8,481,083 prior to the expiration date of United

States Patent Number 8,450,338 and United States Patent Number 8,481,083 and any additional dates of exclusivity; and

e. A permanent injunction enjoining Par and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from seeking, obtaining, or maintaining approval of ANDA No. 205743 until the expiration date of United States Patent Number 8,450,338 and United States Patent Number 8,481,083 and any additional dates of exclusivity.

Dated: February 20, 2015

/s/ Mary W. Bourke
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