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Merck Sharp & Dohme Corp.

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

MERCK SHARP & DOHME CORP. PLAINTIFF, -AGAINST- PAR STERILE PRODUCTS, LLC, PAR PHARMACEUTICAL, INC., AND PAR PHARMACEUTICAL COMPANIES, INC., DEFENDANTS.	Civil Action No. 3:16-cv-00948-PGS-DEA

AMENDED COMPLAINT

Plaintiff Merck Sharp & Dohme Corp. ("Merck"), by and through its undersigned attorneys, for its Complaint against Defendants Par Sterile Products, LLC, Par Pharmaceutical, Inc., and Par Pharmaceutical Companies, Inc. (collectively, "Par" or

"Defendants"), alleges, upon knowledge with respect to their acts and upon information and belief as to other matters, as follows:

Nature of the Action

1. This is an action for patent infringement of U.S. Patent No. 9,023,790 (the "'790 Patent") and U.S. Patent No. 9,358,297 (the "'297 Patent"), arising under the patent laws of the United States, Title 35, United States Code, § 100 et seq., and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application ("ANDA") No. 208768, which Par filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use or sale of a generic version of Merck's NOXAFIL® (Posaconazole) intravenous (infusion) solution, 300 mg/16.7 mL (18 mg/mL) ("Noxafil for Injection"), which is sold in the United States.

Parties

2. Plaintiff Merck is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. Merck is a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve health.

3. Defendant Par Sterile Products, LLC, is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business in Parsippany, New Jersey. Par Sterile Products is a wholly owned subsidiary of Par Pharmaceutical Companies, Inc. Par Sterile Products develops, manufactures and markets branded and generic aseptic injectable products, and

provides contract manufacturing services to the biopharmaceutical and pharmaceutical industry.

4. Defendant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business in Woodcliff Lake, New Jersey. Par Pharmaceutical, Inc. is a wholly owned subsidiary of Par Pharmaceutical Companies, Inc. Par Pharmaceutical, Inc. develops, manufactures, markets and distributes generic pharmaceuticals in the United States.

5. Defendant Par Pharmaceutical Companies, Inc., is a corporation organized and existing under the laws of the State of Delaware, having a place of business in Woodcliff Lake, New Jersey. Par Pharmaceutical Companies, Inc. is a wholly owned subsidiary of Endo International PLC. Par Pharmaceutical Companies, Inc. operates primarily through its wholly owned subsidiary, Par Pharmaceutical, Inc., and specializes in developing, licensing, manufacturing, marketing and distributing generic drugs in the United States.

Jurisdiction and Venue

6. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a).

7. This Court has personal jurisdiction over Defendants by virtue of their presence in and acts within the State of New Jersey.

8. This Court has personal jurisdiction over Defendants because they have purposefully availed themselves of the privilege of selling their pharmaceutical products in the State of New Jersey and, therefore, can reasonably expect to be subject to jurisdiction in New Jersey. Among other things, Defendants conduct marketing and sales activities in the State of New Jersey, including, but not limited to, the distribution,

marketing and sales of pharmaceutical products to New Jersey residents that are continuous and systematic.

9. Defendants are registered to do business in the State of New Jersey, and each has a registered agent there.

10. Defendants collectively share common directors, officers, and/or facilities, operate as agents of each other and act in concert in the design, development, manufacture, distribution and sale of pharmaceutical products throughout the United States, including New Jersey.

11. Defendants acted in concert to develop the generic version of NOXAFIL for Injection and to seek approval from the FDA to sell the product described ANDA 208768 ("the ANDA Product") throughout the United States, including within this District. Defendants state that they intend to engage in the commercial manufacture, use, and/or sale of the ANDA Product before the expiration of the '790 and '297 Patents.

12. Merck's claim for patent infringement arose when Defendants sent the required notice of Par Sterile's ANDA filing to Merck's offices in Rahway, New Jersey.

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

Relevant Facts

14. Merck is the holder of New Drug Application ("NDA") N205596 for the manufacture and sale of posaconazole intravenous solution, which Merck markets and sells under the registered trademark NOXAFIL®. NOXAFIL® for Injection is approved for the prophylaxis of invasive fungal infections in high risk patients.

15. NOXAFIL® for Injection is an embodiment of one or more claims of the '790 Patent. The '790 Patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for NOXAFIL®. The '790 Patent, entitled Posaconazole Intravenous Solution Formulations Stabilized by Substituted ß-Cyclodextrin, was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on May 5, 2015. Its expiry date is July 4, 2031. Merck is the owner of all title, right and interest in and to the '790 Patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A copy of the '790 Patent is attached as Exhibit A.

16. NOXAFIL® for Injection is an embodiment of one or more claims of the '297 Patent. The '297 Patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for NOXAFIL®. The '297 Patent, entitled Posaconazole Intravenous Solution Formulations Stabilized by Substituted ß-Cyclodextrin, was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on June 7, 2016. Its expiry date is June 24, 2031. Merck is the owner of all title, right and interest in and to the '297 Patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A copy of the '297 Patent is attached as Exhibit B.

17. Defendants filed or caused to be filed ANDA No. 208768 with the FDA, seeking FDA approval to market and sell within the United States the ANDA Product before the expiration of the '790 and '297 Patents.

18. Defendants' ANDA No. 208768 identified Merck's NOXAFIL®Injection product and included a written certification, as required by 21

U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the '790 Patent are invalid or otherwise will not be infringed by Defendants' ANDA Product.

19. On about January 7, 2016, Merck received a letter from Par Sterile Products, LLC, dated January 6, 2016, stating that pursuant to §505(j)(2)(B)(ii), Par had submitted to the FDA its ANDA No. 208768. The letter to Merck stated that the '790 Patent is invalid, unenforceable, and/or would not be infringed by the manufacture, use, or sale of the ANDA Product ("First ANDA Notice").

20. Defendants' ANDA No. 208768 identified Merck's NOXAFIL®Injection product and included a written certification, as required by 21 U.S.C. § 355(j)(2)(A)(vii)(IV) , alleging that the claims of the '297 Patent are invalid or otherwise will not be infringed by Defendants' ANDA Product.

21. On about July 6, 2016, Merck received a letter from Par Sterile Products, LLC, dated July 5, 2016, stating that pursuant to §505(j)(2)(B)(ii), Par had submitted to the FDA its ANDA No. 208768. The letter to Merck stated that the '297 Patent is invalid, unenforceable, and/or would not be infringed by the manufacture, use, or sale of the ANDA Product ("Second ANDA Notice").

22. By filing or causing to be filed ANDA No. 208768, Defendants necessarily represented to the FDA that the ANDA Product has the same active ingredient as NOXAFIL®Injection, has the same method of administration, dosage form, and strength as NOXAFIL® and is bioequivalent to NOXAFIL®.

COUNT 1: INFRINGEMENT OF U.S. PATENT NO. 9,023,790

(AGAINST DEFENDANTS)

23. Merck incorporates by reference paragraphs 1-22 of this Complaint as if fully set forth herein.

24. By filing or causing to be filed ANDA No. 208768 with the FDA under 21 U.S.C. §355(j) to obtain approval to engage in the commercial manufacture, use or sale of the ANDA Product before the expiration of the '790 Patent, Defendants committed an act of infringement under 35 U.S.C. § 271(e)(2).

25. The '790 Patent discloses and claims aqueous solutions useful as pharmaceutical compositions of posaconazole for intravenous administration.

26. The First ANDA Notice describes an aqueous solution useful as a pharmaceutical composition of posaconazole for intravenous administration that infringes the '790 Patent.

27. If Defendants commercially make, use, offer to sell or sell the ANDA Product within the United States, or import the ANDA Product into the United States, or induce or contribute to any such conduct during the term of the '790 Patent, Defendants would further infringe the '790 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

28. Merck will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Merck has no adequate remedy at law.

COUNT 2: INFRINGEMENT OF U.S. PATENT NO. 9,358,297

(AGAINST DEFENDANTS)

29. Merck incorporates by reference paragraphs 1-22 of this Complaint as if fully set forth herein.

30. By filing or causing to be filed ANDA No. 208768 with the FDA under 21 U.S.C. §355(j) to obtain approval to engage in the commercial manufacture, use

or sale of the ANDA Product before the expiration of the '297 Patent, Defendants committed an act of infringement under 35 U.S.C. § 271(e)(2).

31. The '297 Patent discloses and claims aqueous solutions useful as pharmaceutical compositions of posaconazole for intravenous administration.

32. The Second ANDA Notice describes an aqueous solution useful as a pharmaceutical composition of posaconazole for intravenous administration that infringes the '297 Patent.

33. If Defendants commercially make, use, offer to sell or sell the ANDA Product within the United States, or import the ANDA Product into the United States, or induce or contribute to any such conduct during the term of the '297 Patent, Defendants would further infringe the '297 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

34. Merck will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Merck has no adequate remedy at law.

Prayer for Relief

WHEREFORE, Plaintiff prays for judgment in its favor and against Defendants and respectfully requests the following relief:

A. A judgment that Defendants have infringed one or more claims of the '790 and '297 Patents under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 208768;

B. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Defendants, their officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing

any product that infringes the '790 or '297 Patents, including the product described in ANDA No. 208768, prior to the expiration of the '790 or '297 Patents, including any extensions;

C. A judgment declaring that making, using, selling, offering to sell, or importing the product described in ANDA No. 208768, or inducing or contributing to such conduct, would constitute infringement of the '790 and '297 Patents by Defendants pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c);

D. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' ANDA No. 208768 be a date that is not earlier than the expiration of the last to expire of the '790 and '297 Patents, or any later expiration of exclusivity to which Merck is or becomes entitled;

E. If Defendants commercially manufacture, use, offer to sell, sell or import the product described in ANDA No. 208768 prior to the expiration of each of the '790 and '297 Patents or any later expiration of exclusivity to which Merck is or becomes entitled, a judgment awarding Merck monetary relief, together with interest;

F. A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and awarding reasonable attorneys' fees, costs and disbursement incurred as a result of this action; and

G. Such other and further relief as the Court deems just and proper.

July 29, 2016

BY

s/ David E. De Lorenzi, Esq.

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