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Plaintiff Merck Sharp & Dohme Corp.

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

MERCK SHARP & DOHME CORP., Plaintiff, -against- ACTAVIS LABORATORIES FL, INC., ANDRX CORPORATION, ACTAVIS PHARMA, INC. and ACTAVIS, INC., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Merck Sharp & Dohme Corp. ("Merck" or "Plaintiff"), by and through its undersigned attorneys, for its Complaint against Defendants, Actavis Laboratories Fl, Inc. ("Actavis Florida"), Andrx Corporation ("Andrx"), Actavis Pharma, Inc. ("Actavis Pharma") and Actavis, Inc. (collectively, "Actavis" or "Defendants"), alleges, upon knowledge with respect to its 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. 5,661,151 (the "'151 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. 207355, which Defendants 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) Delayed Release Tablets, 100 mg, that are sold in the United States.

Parties

2. Plaintiff Merck (formerly known as Schering Corporation) 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 Actavis Florida is a corporation organized and existing under the laws of the State of Florida, having its principal place of business at 4955 Orange Drive, Davie, Florida 33314. Actavis Florida develops and manufactures generic

pharmaceutical products for sale throughout the United States. Actavis Florida is a wholly-owned subsidiary of Andrx.

4. Defendant Andrx is a corporation organized under the laws of the State of Delaware, having its principal place of business at 4955 Orange Drive, Davie, Florida 33314. Andrx markets, distributes and sells pharmaceutical products, including those that are manufactured by Actavis Florida, throughout the United States. Andrx is a wholly-owned subsidiary of Actavis, Inc.

5. Defendant Actavis Pharma is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Actavis Pharma markets, distributes and sells pharmaceutical products, including those that are manufactured by Actavis Florida, throughout the United States. Actavis Pharma is a wholly-owned subsidiary of Actavis, Inc.

6. Defendant Actavis, Inc. is a corporation organized and existing under the laws of the State of Nevada, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Actavis, Inc. markets, distributes and sells pharmaceutical products, including those that are manufactured by Actavis Florida, throughout the United States.

Jurisdiction and Venue

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

8. This Court has personal jurisdiction over Defendants by virtue of their specific acts in, and their systemic and continuous contacts with, the State of New Jersey.

9. 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.

10. Actavis Pharma and Actavis, Inc. have their principal place of business in Parsippany, New Jersey. Actavis Pharma and Actavis, Inc. are registered to do business in the State of New Jersey, and each has a registered agent there.

11. 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.

12. Actavis Florida, Andrx and Actavis Pharma operate as an integrated business ultimately owned and controlled by Actavis, Inc.

13. Defendants have previously submitted to the jurisdiction of the United States District Court for the District of New Jersey in *AstraZeneca AB, et al. v. Andrx Corporation, et al.*, No. 3:14-08030-JAP-TJB (D.N.J.) (Andrx & Actavis, Inc.); *AstraZeneca AB, et al. v. Actavis Laboratories FL, Inc., and Actavis Pharma, Inc.*, No. 3:14-07870-JAP-TJB (D.N.J.) (Actavis Florida & Actavis Pharma); *AstraZeneca AB, et al. v. Actavis Laboratories FL, Inc., and Actavis Pharma, Inc.*, No. 3:14-07263-MLC-TJB (D.N.J.) (Actavis Florida & Actavis Pharma); *Noven Therapeutics, LLC v. Actavis*

Laboratories FL, Inc. et al., No. 2:14-cv-06414 (D.N.J.) (Actavis Florida, Actavis Pharma, Andrx & Actavis, Inc.); *Vivus Inc. et al. v. Actavis Laboratories FL, Inc. et al.*, No. 2:14-cv-03786-FSH-MAH (D.N.J.) (Actavis Florida); and *Supernus Pharmaceuticals, Inc. v. Actavis, Inc., et al.*, No. 13-04740-RMB-JS (D.N.J.) (Actavis Florida, Actavis, Inc. & Actavis Pharma).

14. Defendants acted in concert to develop the generic version of NOXAFIL® and to seek approval from the FDA to sell generic NOXAFIL® throughout the United States, including within this District.

15. Merck's claim for patent infringement arose as the result of Actavis Florida sending the required notice of its ANDA filing to Merck's offices in Rahway, New Jersey. The notice identified the contact information for Actavis Florida's in-house counsel as Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

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

Relevant Facts

17. The '151 Patent, entitled Tetrahydrofuran Antifungals, was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on August 26, 1997. Merck is the owner of all title, right and interest in and to the '151 Patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A copy of the '151 Patent is attached as Exhibit A.

18. Merck is the holder of New Drug Application ("NDA") No. 205053 for the manufacture and sale of Posaconazole Delayed Release Tablets, which Merck markets and sells under the registered trademark NOXAFIL®.

NOXAFIL® is an embodiment of one or more of the claims of the '151 Patent. The '151 Patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for NOXAFIL®.

19. Defendants filed or caused to be filed ANDA No. 207355 with the FDA, seeking FDA approval to market and sell within the United States a generic Posaconazole Delayed Release tablets, 100 mg (the "ANDA Product"), prior to the expiration of the '151 Patent.

20. Defendants' ANDA No. 207355 purportedly identified Merck's NOXAFIL® product and included a written certification, as required by 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "ANDA Certification"), alleging that the claims of the '151 Patent are invalid or otherwise will not be infringed by Defendants' ANDA Product.

21. By filing or causing to be filed ANDA No. 207355, Defendants necessarily represented to the FDA that the ANDA Product has the same active ingredient as NOXAFIL®, has the same method of administration, dosage form, and strength as NOXAFIL® and is bioequivalent to NOXAFIL®.

22. On June 25, 2015, Merck received a letter from Actavis Florida stating that Actavis Florida had filed ANDA No. 207355 prior to the expiration of the '151 Patent (the "ANDA Notice"). The ANDA Notice included notice of Actavis Florida's allegations that the '151 Patent is invalid, unenforceable and/or not infringed by Defendants' ANDA Product.

23. Defendants' submission of ANDA No. 207355, including the ANDA Certification, to the FDA constitutes infringement of the '151 Patent under 35 U.S.C. § 271(e)(2). Moreover, Defendants' anticipated commercial manufacture, use,

sale, offer for sale or importation of the ANDA Product will infringe the '151 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

24. Merck commenced this action within 45 days of receiving the ANDA Notice.

COUNT 1: INFRINGEMENT OF U.S. PATENT 5,661,151

25. Merck incorporates by reference paragraphs 1-24 of this Complaint as if fully set forth herein.

26. By filing or causing to be filed ANDA No. 207355 to the FDA under 21 U.S.C. § 355(b)(2) in order to engage in the commercial manufacture, use or sale of the ANDA Product before the expiration of the '151 Patent, Defendants committed an act of infringement under 35 U.S.C. § 271(e)(2).

27. The '151 Patent discloses and claims chemical compounds, including posaconazole, pharmaceutical compositions comprising those compounds and methods of treating and/or preventing fungal infections comprising the administration of an effective amount of those compounds.

28. The ANDA Notice describes the active ingredient of the drug product for which Defendants seek FDA approval as posaconazole, whose manufacture, sale, offer to sell, or importation within the United States infringes the '151 Patent.

29. 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 '151 Patent, Defendants would further infringe the '151 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

30. 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, Merck prays for a judgment in its favor and against Defendants and respectively requests the following relief:

A. A judgment that Defendants have infringed one or more claims of the '151 Patent under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 207355;

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 '151 Patent, including the product described in ANDA No. 207355, prior to the expiration of the '151 Patent, including any extensions;

C. A judgment declaring that making, using, selling, offering to sell, or importing the product described in ANDA No. 207355, or inducing or contributing to such conduct, would constitute infringement of the '151 Patent 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. 207355 be a date that is not earlier than the expiration of the '151 Patent 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. 207355 prior to the expiration of the

'151 Patent 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.

August 6, 2015

by /s/ David E. De Lorenzi
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