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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IMPAX LABORATORIES, INC., Plaintiff, v. ACTAVIS LABORATORIES FL, INC. and ACTAVIS PHARMA INC., Defendants.	)	Civil Action No. _____

COMPLAINT

Plaintiff, Impax Laboratories, Inc. ("Impax"), by its undersigned attorneys, for its Complaint against Defendants Actavis Laboratories FL, Inc., and Actavis Pharma, Inc. (collectively, "Actavis"), hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants' submissions of Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Plaintiff's RYTARY® (Levodopa/Carbidopa) capsules prior to the expiration of United States Patent No. 9,901,640.

THE PARTIES

2. Plaintiff Impax Laboratories, Inc. ("Impax") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 30831 Huntwood Avenue, Hayward, CA 94544.

3. On information and belief, Defendant Actavis Laboratories FL, Inc. ("Actavis FL") is a corporation organized and existing under the laws of the State of Florida, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054.

4. On information and belief, Actavis FL is in the business of preparing, manufacturing, and distributing pharmaceutical products throughout the United States, including the State of New Jersey.

5. On information and belief, Defendant Actavis Pharma Inc. ("Actavis Pharma") is a corporation organized and existing under the laws of Delaware, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054.

6. On information and belief, Actavis Pharma is in the business of, among other things, marketing and distributing pharmaceutical products, including pharmaceutical products manufactured by Actavis FL, throughout the United States, including the State of New Jersey.

7. On information and belief, the acts of Actavis FL complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation, or assistance of, or at least in part for the benefit of, Actavis Pharma.

8. Actavis FL and Actavis Pharma are collectively referred to hereinafter as "Actavis."

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

10. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

PERSONAL JURISDICTION OVER ACTAVIS FL

11. Plaintiff realleges all preceding paragraphs as if fully set forth herein.

12. On information and belief, Actavis FL develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

13. This Court has personal jurisdiction over Defendant Actavis, FL because, *inter alia*, Actavis FL, on information and belief: (1) has substantial, continuous, and systematic contacts with this State; (2) intends to market, sell, and/or distribute Actavis's infringing ANDA products to residents of this State; (3) maintains a principal place of business in this State; (4) maintains a broad distributorship network within this State; and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State.

14. Additionally, on information and belief, Actavis FL has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district, including in related matters. *See Impax Labs, Inc. v. Actavis Labs FL, Inc. et al.*, No. 15-cv-6934-SRC-CLW (consolidated) (D.N.J.).

15. Additionally, on information and belief, Actavis FL has availed itself of the legal protections of the State of New Jersey, by, among other things, indicating in the Offer for Confidential Access in the Paragraph IV Certifications accompanying ANDA No. 208522 regarding related patents currently at issue in related matters before this Court (Civil Action No. 15-6934 (SRC)(CLW) (consolidated)), that "[t]his Offer of Confidential Access shall be governed by the laws of the State of New Jersey."

PERSONAL JURISDICTION OVER ACTAVIS PHARMA

16. Plaintiff realleges all preceding paragraphs as if fully set forth herein.

17. On information and belief, Actavis Pharma develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

18. This Court has personal jurisdiction over Actavis Pharma because, *inter alia*, Actavis Pharma, on information and belief: (1) has substantial, continuous, and systematic contacts with this State; (2) is registered to do business in the State of New Jersey under entity ID 0100573928; (3) intends to market, sell, and/or distribute Actavis's infringing ANDA products to residents of this State; (4) maintains a principal place of business in this State; (5) maintains a broad distributorship network within this State; and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State.

19. Additionally, on information and belief, Actavis Pharma has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction, including in related cases (*Impax Labs, Inc. v. Actavis Labs FL, Inc. et al.*, No. 15-cv-6934-SRC-CLW (consolidated) (D.N.J.)), and has availed itself of this judicial district through the assertion of counterclaims.

BACKGROUND

U.S. Patent No. 9,901,640

20. On February 27, 2018, the PTO duly and legally issued United States Patent No. 9,901,640 ("the '640 patent") entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou and Laman Alani. A true and correct copy of the '640 patent is attached as Exhibit 1.

RYTARY®

21. Impax is the holder of New Drug Application ("NDA") No. 203312 ("the NDA") for carbidopa and levodopa capsules, for oral use, in 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, 61.25 mg/245 mg dosages, which is sold under the trade name RYTARY®.

22. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the ’640 patent is listed in the FDA’s Approved Drug Products with Therapeutic Evaluations (“Orange Book”) with respect to RYTARY®.

ACTS GIVING RISE TO THIS ACTION

COUNT I - INFRINGEMENT OF THE ’640 PATENT BY ACTAVIS

23. Plaintiff realleges all preceding paragraphs as if fully set forth herein.

24. On information and belief, Actavis submitted ANDA No. 208522 (the “Actavis ANDA”) to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market carbidopa/levodopa extended release capsules, for oral use, in 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, 61.25 mg/245 mg dosages (the “Actavis ANDA Product”).

25. Actavis ANDA No. 208522 refers to and relies upon the RYTARY® NDA and contains data that, according to Actavis, demonstrate the bioequivalence of the Actavis ANDA Product and RYTARY®.

26. Plaintiff received a letter from Actavis on or about April 16, 2018, stating that Actavis has included a certification in the Actavis ANDA, pursuant to 21 U.S.C. § 355(J)(2)(A)(vii)(IV), that inter alia, certain claims of the ‘640 patent are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Actavis ANDA Products (the “Actavis Paragraph IV Certification”).

27. Actavis has infringed at least one claim of the ’640 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Actavis ANDA, by which Actavis

seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Actavis ANDA Products prior to the expiration of the '640 patent.

28. Actavis has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Actavis ANDA Products in the event that the FDA approves the Actavis ANDA. Accordingly, an actual and immediate controversy exists regarding Actavis's infringement of the '640 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

29. Actavis's manufacture, use, offer to sell, or sale of the Actavis ANDA Products in the United States or importation of the Actavis ANDA Products into the United States during the term of the '640 patent would further infringe at least one claim of the '640 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

30. On information and belief, the Actavis ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '640 patent either literally or under the doctrine of equivalents.

31. On information and belief, the use of the Actavis ANDA Products constitute a material part of at least one of the claims of the '640 patent; Actavis knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '640 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

32. On information and belief, the offering to sell, sale, and/or importation of the Actavis ANDA Products would contributorily infringe at least one of the claims of the '640 patent, either literally or under the doctrine of equivalents.

33. On information and belief, Actavis had knowledge of the '640 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '640 patent, either literally or under the doctrine of equivalents.

34. On information and belief, the offering to sell, sale, and/or importation of the Actavis ANDA Products would actively induce infringement of at least one of the claims of the '640 patent, either literally or under the doctrine of equivalents.

35. Plaintiff will be substantially and irreparably harmed if Actavis is not enjoined from infringing the '640 patent.

36. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Impax's reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully request that the Court enter judgment against Defendants and for the following relief:

a. A Judgment be entered that Actavis has infringed at least one claim of the '640 patent by submitting the Actavis ANDA;

b. That Defendants, their officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from be preliminarily and permanently enjoined

from: (i) engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs or drugs for use in methods of administering drugs claimed in the '640 patent, and (ii) seeking, obtaining or maintaining approval of ANDA until the expiration of the '640 patent or such other later time as the Court may determine;

c. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '640 patent, including any extensions;

d. That Impax be awarded monetary relief if Defendants commercially use, offer to sell, or sell their respective proposed generic versions of RYTARY® or any other product that infringes or induces or contributes to the infringement of the '640 patent, within the United States, prior to the expiration of that patent, including any extensions, and that any such monetary relief be awarded to Impax with prejudgment interest;

e. Costs and expenses in this action; and

f. Such other and further relief as the Court deems just and appropriate.

Dated: May 17, 2018

Respectfully submitted,

s/ Michael E. Patunas

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RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, the matter in controversy is related to the following matters: *Impax Labs, Inc. v. Actavis Labs FL, Inc. et al.*, No. 15-cv-6934-SRC-CLW (consolidated), pending in the United States District Court for the District of New Jersey.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding other than the above referenced matter, nor are there any non-parties known to Plaintiff that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: May 17, 2018

PATUNAS LAW LLC

s/ Michael E. Patunas

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RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief.

Dated: May 17, 2018

PATUNAS LAW LLC

s/ Michael E. Patunas

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