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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IMPAX LABORATORIES, INC., Plaintiff, v. ZYDUS PHARMACEUTICALS USA, INC. and CADILA HEALTHCARE LTD., Defendants.	)	Civil Action No. _____

COMPLAINT

Plaintiff, Impax Laboratories, Inc. ("Impax"), by its undersigned attorneys, for its Complaint against Defendants Zydus Pharmaceuticals USA, Inc. and Cadila Healthcare Ltd., 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. 9,089,608.

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 Zydus Pharmaceuticals USA, Inc. ("Zydus USA") is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 73 Route 31 N., Pennington, New Jersey 08534.

4. On information and belief, Zydus USA is registered to do business in the State of New Jersey under entity ID # 0100915422, and is registered as a Wholesale Drug & Medical Device wholesaler by the New Jersey Department of Health and Senior Services.

5. On information and belief, Zydus USA is in the business of, among other things, developing, preparing, manufacturing, selling, marketing and distributing generic pharmaceutical products throughout the United States, including the State of New Jersey.

6. On information and belief, Zydus USA has consented to this Court's jurisdiction and asserted counterclaims in *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, No. 3:10-cv-01723-JAP-TJB (D.N.J. June 15, 2010); *Roxane Labs, Inc. v. Zydus Pharms. (USA) Inc*., No. 2:14-cv-05423-SRC-CLW (D.N.J. Oct. 7, 2014), and *Boehringer Ingelheim Pharms. Inc. v. HEC Pharm.*, No. 15-5982 (PGS)(TJB).

7. On information and belief, Defendant Cadila Healthcare Ltd. (d/b/a Zydus Cadila) ("Zydus Cadila") is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015, Gujarat, India.

8. On information and belief, Zydus USA is a wholly-owned subsidiary of Zydus Cadila.

9. On information and belief, Zydus Cadila has consented to this Court's jurisdiction and has asserted counterclaims in the following matters: *Takeda Pharmaceutical Co. v. Zydus Pharmaceuticals (USA) Inc*., No. 3:10-cv-01723-JAP-TJB (D.N.J. June 15, 2010) and *Boehringer Ingelheim Pharmaceuticals Inc. v. HEC Pharm Group*, No. 3:15-cv-5982 (PGS)(TJB) (D.N.J. Sept. 16, 2015).

10. On information and belief, the acts of Zydus USA complained of herein were done with the cooperation, participation, and assistance of Zydus Cadila.

11. Zydus USA and Zydus Cadila are collectively referred to hereinafter as "Zydus" or "Defendants."

PERSONAL JURISDICTION OVER ZYDUS USA

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

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

14. This Court has personal jurisdiction over Defendant Zydus USA because, *inter alia*, Zydus USA, on information and belief: (1) has substantial, continuous, and systematic contacts with this State; (2) intends to market, sell, and/or distribute Zydus'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.

15. Additionally, on information and belief, Zydus USA 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 Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, No. 3:10-cv-01723-JAP-TJB (D.N.J. June 15, 2010); *Roxane Labs, Inc. v. Zydus Pharms. (USA) Inc.*, No. 2:14-cv-05423-SRC-CLW (D.N.J. Oct. 7, 2014), and *Boehringer Ingelheim Pharms. Inc. v. HEC Pharm.*, No. 15-5982 (PGS)(TJB) (D.N.J. Sept. 16, 2015).

16. On information and belief, Zydus USA has availed itself of the rights and benefits of the State of New Jersey by, among other things, incorporating in this State, by registering to do business in the State of New Jersey under entity ID # 0100915422, and registering as a Wholesale Drug & Medical Device wholesaler by the New Jersey Department of Health and Senior Services.

17. Additionally, on information and belief, Zydus USA 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. 210911 regarding the patents at issue herein, that "[t]his Agreement shall be governed in accordance with the laws of the state of New Jersey without regard to its conflict-of-state laws."

PERSONAL JURISDICTION OVER ZYDUS CADILA

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

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

20. This Court has personal jurisdiction over Zydus Cadila because, *inter alia*, Zydus Cadila, on information and belief: (1) intends to market, sell or distribute Zydus' ANDA products to residents of this state; (2) controls Defendant Zydus USA; (3) operates through its wholly owned subsidiary Zydus USA, which is incorporated and maintains a principal place of business in New Jersey; (4) makes its generic drug product available 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.

21. Furthermore, this Court has personal jurisdiction over Zydus Cadila because, on information and belief, Zydus Cadila has participated in the preparation and/or submission of ANDA No. 210911.

22. Additionally, on information and belief, Zydus Cadila has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction, including in *Takeda Pharmaceutical Co. v. Zydus Pharmaceuticals (USA) Inc.*, No. 3:10-cv-01723-JAP-TJB (D.N.J. June 15, 2010) and *Boehringer Ingelheim Pharmaceuticals Inc. v. HEC Pharm Group*, No. 3:15-cv-5982 (PGS)(TJB) (D.N.J. Sept. 16, 2015), and has availed itself of this judicial district through the assertion of counterclaims.

23. Alternatively, to the extent the above facts do not establish personal jurisdiction over Zydus Cadila, this Court may exercise jurisdiction over Zydus Cadila pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiff's claims arise under federal law; (b) Zydus Cadila would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Zydus Cadila has sufficient contacts with the United States as a whole, including, but not limited to,

manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Zydus Cadila satisfies due process.

VENUE

24. 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).

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

26. Venue is proper against Zydus USA because, on information and belief, Zydus is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 73 Route 31 N., Pennington, New Jersey 08534, and is furthermore registered to do business in the State of New Jersey.

27. Venue is proper against Zydus Cadila, as it is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015, Gujarat, India, and is therefore not a resident of the United States. Additionally, as described above, this Court has personal jurisdiction over Zydus Cadila.

BACKGROUND
U.S. Patent No. 9,089,608

28. On June 28, 2015, the PTO duly and legally issued United States Patent No. 9,089,608 ("the '608 patent") entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou and Laman Lynn Alani. A true and correct copy of the '608 patent is attached as Exhibit 1.

RYTARY®

29. 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®.

30. RYTARY® is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database ("Orange Book") as having New Dosage Form Exclusivity until January 7, 2018.

31. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '608 patent is listed in the "Orange Book" with respect to RYTARY®.

32. RYTARY® is an extended-release treatment for Parkinson's disease.

33. Patients with Parkinson's disease sometimes experience dyskinesia, a form of involuntary movement that may get in the way of a patient's daily activities.

34. Patients with the disease also experience "on" times and "off" times when taking medication to treat Parkinson's disease. "On" time is when a patient's symptoms are less apparent and a patient is able to go about his or her day. "Off" time is when a patient's medication is not working and a patient must cope with his or her symptoms—which may include a patient feeling stiff or moving slowly.

35. Patients with early Parkinson's disease who took RYTARY® experienced a significant improvement in their ability to move and perform activities throughout the day, while patients with advanced Parkinson's disease who took RYTARY® experienced significantly less "off" time, with more "on" time without troublesome dyskinesia during the day.

ACTS GIVING RISE TO THIS ACTION

COUNT I - INFRINGEMENT OF THE '608 PATENT BY ZYDUS

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

37. On information and belief, Zydus submitted ANDA No. 210911 (the "Zydus 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 "Zydus ANDA Product").

38. Zydus ANDA No. 210911 refers to and relies upon the RYTARY® NDA and contains data that, according to Zydus, demonstrate the bioequivalence of the Zydus ANDA Product and RYTARY®.

39. Plaintiff received a letter from Zydus on or about November 6, 2017, stating that Zydus has included a certification in the Zydus ANDA, pursuant to 21 U.S.C. § 355(J)(2)(A)(vii)(IV), that inter alia, certain claims of the '608 patent will not be infringed by the commercial manufacture, use, or sale of the Zydus ANDA Products (the "Zydus Paragraph IV Certification").

40. In accordance with 21 U.S.C. § 355(j)(5)(B)(iii), Plaintiff has brought this action for infringement of the '608 patent against Defendants within 45 days after the date on which the Zydus Paragraph IV Certification was received.

41. Zydus has infringed at least claim 21 of the '608 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Zydus ANDA, by which Zydus seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Zydus ANDA Products prior to the expiration of the '608 patent.

42. The Zydus Paragraph IV Certification does not include a non-infringement argument with respect to claim 21 of the '608 patent.

43. Zydus has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Zydus ANDA Products in the event that the FDA

approves the Zydus ANDA. Accordingly, an actual and immediate controversy exists regarding Zydus's infringement of the '608 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

44. Zydus's manufacture, use, offer to sell, or sale of the Zydus ANDA Products in the United States or importation of the Zydus ANDA Products into the United States during the term of the '608 patent would further infringe at least claim 21 of the '608 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

45. On information and belief, the Zydus 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 claim 21 of the '608 patent either literally or under the doctrine of equivalents.

46. On information and belief, the use of the Zydus ANDA Products constitute a material part of at least claim 21 of the '608 patent; Zydus knows that its ANDA Products are especially made or adapted for use in infringing at least claim 21 of the '608 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.

47. On information and belief, the offering to sell, sale, and/or importation of the Zydus ANDA Products would contributorily infringe at least one claim 21 of the '608 patent, either literally or under the doctrine of equivalents.

48. On information and belief, Zydus had knowledge of the '608 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 claim 21 of the '608 patent, either literally or under the doctrine of equivalents.

49. On information and belief, the offering to sell, sale, and/or importation of the Zydus ANDA Products would actively induce infringement of at least one of the claims of the '608 patent, either literally or under the doctrine of equivalents.

50. Plaintiff will be substantially and irreparably harmed if Zydus is not enjoined from infringing the '608 patent.

51. 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 Zydus has infringed at least one claim of the '608 patent by submitting the Zydus 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 '608 patent, and (ii) seeking, obtaining or maintaining approval of the Zydus ANDA until the expiration of the '608 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 '608 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 '608 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: December 21, 2017

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) and *Impax Labs., Inc. v. Sandoz, Inc.*, No. 17-cv-02227-SRC-CLW, both 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: December 21, 2017

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: December 21, 2017

PATUNAS LAW LLC

s/ Michael E. Patunas

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