IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No. _____
ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LTD. (d/b/a ZYDUS CADILA),	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Amgen Inc. ("Amgen") by way of Complaint against Defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (d/b/a Zydus Cadila) (collectively, "Defendants") alleges as follows:

PARTIES

1. Amgen is a corporation organized and existing under the laws of the State of Delaware. Its principal place of business is located at One Amgen Center Drive, Thousand Oaks, California 91320-1799. Amgen discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry.

2. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") is a New Jersey corporation, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

3. Upon information and belief, Defendant Cadila Healthcare Ltd. ("Cadila") is an Indian corporation, having a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad-380015, Gujarat, India.

4. Upon information and belief, Zydus USA is a wholly owned subsidiary of Cadila, and is controlled and/or dominated by Cadila.

5. Upon information and belief, Defendants regularly transact business within Delaware, including but not limited to, through Cadila's direction of the operations and management of Zydus USA, as well as Cadila shipping generic drugs to Zydus USA from locations outside the United States for marketing, sale and distribution by Zydus USA within the United States generally, and Delaware specifically.

NATURE OF THE ACTION

6. This is a civil action for infringement of U.S. Patent No. 9,375,405 (the "'405 patent").

7. This action is based upon the Patent Laws of the United States, 35 U.S.C. §1 *et seq.* and arises out of Zydus USA's filing of an Abbreviated New Drug Application ("ANDA") No. 208971 seeking approval to manufacture, use and/or sell cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) ("Defendants' ANDA products") prior to the expiration of the '405 patent, which is assigned to Amgen and listed in the publication entitled *Approved Drug Products with Therapeutic Equivalents* (the "Orange Book") as covering SENSIPAR®.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States and the Food and Drug laws of the United States, Titles 35 and 21, United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

9. This Court has jurisdiction over Zydus USA and Cadila because, *inter alia*, upon information and belief, Zydus USA and Cadila are working in concert for purposes of developing, formulating, manufacturing, marketing, and selling drug products throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA products. Upon information and belief, Zydus USA and Cadila acted in concert to file ANDA No. 208971 seeking approval to engage in the commercial manufacture, use, sale, and/or importation of Defendants' ANDA products in the United States, including in Delaware. Upon information and belief, Zydus USA and Cadila, acting in concert and/or as agents of one another, will market, distribute, and/or sell Defendants' ANDA products in the United States, including in Delaware, upon approval of ANDA No. 208971, and will derive substantial revenue from the use or consumption of Defendants' ANDA products in the State of Delaware.

10. In the alternative, this Court has jurisdiction over Cadila because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met. This Court has jurisdiction over Cadila because, *inter alia*, this action arises from actions of Cadila directed toward Delaware, and because Cadila has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Cadila regularly and continuously transacts business within the State of Delaware, including by selling pharmaceutical products in Delaware, either on its own or through its affiliates. Upon information and belief, Cadila derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

11. This Court has jurisdiction over Defendants because, *inter alia*, upon information and belief, Defendants have previously been sued in this judicial district without

objecting on the basis of lack of personal jurisdiction and have availed themselves of Delaware courts through the assertions of counterclaims in suits brought in Delaware. *See, e.g., Upsher-Smith Laboratories, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al.*, Civil Action No. 16-248 (D. Del.); *Forest Laboratories, Inc. et al. v. Apotex Corp et al.*, Civil Action No. 14-200 (D. Del.).

12. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

THE PATENT-IN-SUIT

13. United States Patent No. 9,375,405, entitled "Rapid Dissolution Formulation of Calcium Receptor-Active Compound," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on June 28, 2016. A copy of the '405 patent is attached hereto as Exhibit A.

14. The '405 patent is assigned to Amgen and Amgen is the owner of the '405 patent.

15. Amgen holds an approved New Drug Application ("NDA") No. 21-688 for cinacalcet hydrochloride tablets which the U.S. Food and Drug Administration ("FDA") approved on March 8, 2004. Cinacalcet hydrochloride is a calcium receptor-active compound.

16. Amgen sells various dosage strengths of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) in the United States under the tradename SENSIPAR®.

17. The '405 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-688.

18. The claims of the '405 patent are directed to pharmaceutical compositions comprising cinacalcet hydrochloride.

BACKGROUND ON SENSIPAR®

19. Cinacalcet hydrochloride is the active ingredient in SENSIPAR®, a medication marketed and sold in tablet form by Amgen. Amgen received FDA approval to market SENSIPAR® on March 8, 2004 to treat secondary hyperparathyroidism ("HPT") in patients with chronic kidney disease (CKD) on dialysis and hypercalcemia in patients with parathyroid carcinoma.

20. Secondary HPT is a condition that is caused when the parathyroid glands located in the neck produce too much parathyroid hormone in response to low blood calcium and is associated with CKD patients. Cinacalcet hydrochloride helps to lower the amount of parathyroid hormone, calcium, and phosphorus concentrations in the blood.

21. Cinacalcet hydrochloride is also indicated for use in lowering calcium levels in the blood for patients with parathyroid cancer. Patients with parathyroid cancer can develop severe hypercalcemia (an excessive amount of calcium in the blood). Removal of the parathyroid was the only available therapy for parathyroid cancer before SENSIPAR®.

22. Cinacalcet hydrochloride (SENSIPAR®) is a first-in-class molecule developed by scientists to treat an unmet need in patients suffering from CKD and parathyroid carcinoma.

23. On February 25, 2011, Amgen also received FDA approval to market SENSIPAR® to treat severe hypercalcemia in patients with primary HPT who are unable to undergo parathyroidectomy.

ACTS GIVING RISE TO THIS ACTION

24. Upon information and belief, Defendants reviewed certain commercial and economic information regarding Amgen's SENSIPAR® and decided to file an ANDA seeking approval to market a generic version of SENSIPAR®.

25. Upon information and belief, Defendants collaborated in the research, development, preparation, and filing of ANDA No. 208971 for generic cinacalcet hydrochloride tablets EQ 30 mg, EQ 60 mg, and 90 mg.

26. On February 6, 2017, Amgen received a letter dated February 3, 2017, from Zydus USA notifying Amgen that Zydus USA had filed ANDA No. 208971 with the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to commercially manufacture, use, sell, and/or import a generic version of Amgen's SENSIPAR® prior to the expiry of the '405 patent.

27. The stated purpose of Zydus USA's February 3, 2017 letter was to notify Amgen that ANDA No. 208971 included a certification under 21 U.S.C. §355(j)(2)(a)(vii)(IV) ("Paragraph IV Certification") that the claims of the '405 patent are invalid or will not be infringed by the commercial manufacture, use, sale, offer for sale, and/or import of Defendants' products. Attached to the February 3, 2017, letter was a "Detailed Statement" of the factual and legal basis for Zydus USA's Paragraph IV Certification.

28. Upon information and belief, Defendants were aware of the '405 patent when Zydus USA notified Amgen of its Paragraph IV Certification of the '405 patent.

29. Amgen commenced this action within 45 days of receipt of the letter.

FIRST CLAIM FOR RELIEF

30. Amgen incorporates and realleges paragraphs 1-29 above, as if set forth specifically here.

31. Upon information and belief, Zydus USA filed ANDA No. 208971 with the FDA under the provisions of 21 U.S.C. § 355(j).

32. Upon information and belief, Zydus USA's ANDA No. 208971 seeks FDA approval to engage in the commercial manufacture, use, sale, and/or importation of Defendants' ANDA products (generic cinacalcet hydrochloride tablets, EQ 30 mg, EQ 60 mg, and EQ 90 mg base) before the expiration of the '405 patent.

33. On February 6, 2017, Amgen received a letter from Zydus USA dated February 3, 2017, purporting to be a Notice of Certification for ANDA No. 208971 under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(i) and (ii), and 21 C.F.R. § 314.95(a)-(c).

34. Zydus USA's letter alleges that the active ingredient in Defendants' ANDA products for which it seeks approval is cinacalcet hydrochloride.

35. Upon information and belief, Zydus USA has made and included in its ANDA a Certification under 21 U.S.C. § 355(j)(2)(A)(vii)(iv) that, in its opinion and to the best of its knowledge, the '405 patent is invalid, not infringed and/or unenforceable.

36. Defendants' submission of ANDA No. 208971 to obtain approval to engage in the commercial manufacture, use, sale, and/or importation of Defendants' ANDA products prior to the expiration of the '405 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

37. Upon information and belief, Defendants' ANDA products would infringe, either literally or under the doctrine of equivalents, at least claim 1 of the '405 patent.

38. Upon information and belief, Amgen is entitled to full relief from Defendants' acts of infringement of the '405 patent under 35 U.S.C. § 271(e)(4).

SECOND CLAIM FOR RELIEF

39. Amgen incorporates and realleges paragraphs 1-38 above, as if set forth specifically here.

40. Upon information and belief, Defendants have made substantial preparations to sell Defendants' ANDA products.

41. Upon information and belief, Defendants intend to commence sale of Defendants' ANDA products immediately upon receiving approval from the FDA.

42. Upon information and belief, the manufacture, use, sale, offer for sale, and importation of Defendants' ANDA products, once approved by the FDA, will infringe, either literally or under the doctrine of equivalents, induce and/or contribute to the infringement of at least claim 1 of the '405 patent under 35 U.S.C. § 271(a), (b) and/or (c).

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

44. An actual controversy exists relating to Defendants' threatened infringement of the '405 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Amgen respectfully requests the following relief:

A. A Judgment that the claims of the ’405 patent are not invalid, are not unenforceable, and are infringed by Defendants’ submission of ANDA No. 208971, and that Defendants’ making, using, offering to sell, or selling in the United States, or importing into the United States Defendants’ ANDA products will infringe the ’405 patent.

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 208971 shall be a date which is not earlier than the expiration date of the ’405 patent, including any extensions and/or additional periods of exclusivity to which Amgen is or becomes entitled.

C. An order permanently enjoining Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Defendants’ ANDA products until after the expiration of the ’405 patent, including any extensions and/or additional periods of exclusivity to which Amgen is or becomes entitled.

D. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Amgen costs, expenses and disbursements in this action, including reasonable attorney fees.

E. Such further and other relief as this Court deems proper and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Amgen Inc.

OF COUNSEL:

John D. Murnane
Joshua I. Rothman
Alicia A. Russo
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, NY 10104-3800
(212) 218-2100

Wendy A. Whiteford
Lois M. Kwasigroch
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
(805) 447-1000

February 21, 2017