IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
THE ACME LABORATORIES LTD.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Amgen Inc. ("Amgen") by way of Complaint against Defendant The ACME Laboratories Ltd. ("ACME") 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, ACME is an Indian corporation, having its principal place of business at Court de la ACME 1/4, Kallayanpur, Mirpur Road, Dhaka-1207, Bangladesh, India.

3. Upon information and belief, ACME, through its U.S. agent, has submitted to the United States Food and Drug Administration ("FDA") Abbreviated New Drug Application ("ANDA") No. 213325.

NATURE OF THE ACTION

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

5. This action is based upon the Patent Laws of the United States, 35 U.S.C. §1 *et seq.* and arises out of the submission of ANDA No. 213325 seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) ("ACME's 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

6. 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.

7. This Court has jurisdiction over ACME. Upon information and belief, ACME, through its U.S. agent, filed ANDA No. 213325. Upon information and belief, ACME will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA products in the United States, including in Delaware, upon approval of ANDA No. 213325, and will derive substantial revenue from the use or consumption of its ANDA products in the State of Delaware.

8. In the alternative, this Court has jurisdiction over ACME under Federal Rule of Civil Procedure 4(k)(2)(A) because (i) Plaintiff's claims arise under federal law; (ii) ACME is a

foreign defendant not subject to general personal jurisdiction in the courts of any state; and (iii) ACME has sufficient contacts with the United States as a whole, including but not limited to preparing and directing the submission of ANDA No. 213325 to the FDA, such that this Court's exercise of jurisdiction over ACME satisfies due process.

9. Venue is proper in this Court under 28 U.S.C. § 1391(b).

THE PATENT-IN-SUIT

10. On June 28, 2016, the '405 patent, titled "Rapid Dissolution Formulation of a Calcium Receptor-Active Compound," was duly and legally issued by the United States Patent and Trademark Office ("PTO").

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

12. Amgen is the holder of an approved New Drug Application ("NDA") No. 21-688 for cinacalcet hydrochloride tablets which the FDA approved on March 8, 2004. Cinacalcet hydrochloride is a calcium receptor-active compound.

13. 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®.

14. The '405 patent is listed in the Orange Book for NDA No. 21-688.

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

BACKGROUND ON SENSIPAR®

16. 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® (cinacalcet hydrochloride) 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.

17. 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. SENSIPAR® helps to lower the amount of parathyroid hormone, calcium, and phosphorus concentrations in the blood.

18. SENSIPAR® 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®.

19. SENSIPAR® is a first-in-class drug developed by scientists to treat an unmet need in patients suffering from secondary HPT and parathyroid carcinoma

20. 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 FOR INFRINGEMENT OF THE PATENT-IN-SUIT

21. Upon information and belief, ACME 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®.

22. On July 30, 2019, Amgen received a letter dated July 29, 2019, from ACME notifying Amgen that ACME's U.S. agent Global Regulatory Support, Inc. had submitted ANDA No. 213325 to the FDA for ACME under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to engage in the commercial manufacture, use, offer

for sale, sale, and/or importation of a generic version of Amgen's SENSIPAR® prior to the expiry of the '405 patent.

23. The stated purpose of ACME's July 29, 2019 letter was to notify Amgen that ANDA No. 213325 included a certification ("Paragraph IV Certification") that the claims of the '405 patent are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of ACME's ANDA Products. Included with the July 29, 2019 letter was a detailed statement of the factual and legal basis for ACME's Paragraph IV Certification.

24. Upon information and belief, ACME was aware of the '405 patent when it notified Amgen of its Paragraph IV Certification of the '405 patent.

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

FIRST CLAIM FOR RELIEF

26. Amgen incorporates and realleges paragraphs 1-25 above, as if set forth specifically here.

27. Upon information and belief, ACME, through its U.S. agent, filed ANDA No. 213325 with the FDA under the provisions of 21 U.S.C. § 355(j).

28. Upon information and belief, ACME's ANDA No. 213325 seeks FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of ACME's ANDA products (generic cinacalcet hydrochloride tablets, EQ 30 mg, EQ 60 mg, and EQ 90 mg base) before the expiration of the '405 patent.

29. On July 30, 2019, Amgen received a letter from ACME dated July 29, 2019, purporting to be a Notice of Certification for ANDA No. 213325 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(c).

30. ACME's letter alleges that the active ingredient in ACME's ANDA products for which it seeks approval is cinacalcet hydrochloride.

31. Upon information and belief, ACME 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.

32. ACME's submission of ANDA No. 213325 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of ACME's ANDA products prior to the expiration of the '405 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

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

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

SECOND CLAIM FOR RELIEF

35. Amgen incorporates and realleges paragraphs 1-34 above, as if set forth specifically here.

36. Upon information and belief, ACME has made substantial preparations to sell ACME's ANDA products.

37. Upon information and belief, ACME intends to commence sale of ACME's ANDA products immediately upon receiving approval from the FDA.

38. Upon information and belief, the manufacture, use, sale, offer for sale, and/or importation of ACME's 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).

39. 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.

40. An actual controversy exists relating to ACME's 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 ACME's submission of ANDA No. 213325 under 35 U.S.C. § 271 (e)(2)(A), and that the commercial manufacture, use, offer for sale, sale, and/or importation of ACME's ANDA products prior to the expiration of the '405 patent will infringe the '405 patent.

B. An order under 35 U.S.C. § 271 (e)(4)(A) that the effective date of any FDA approval of ANDA No. 213325 shall be a date that is not earlier than the expiration date of the '405 patent, including extensions and/or additional periods of exclusivity to which Amgen is or becomes entitled.

C. An order permanently enjoining ACME, its affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or concert with it, from making, using, offering to sell, or selling in the United States, or importing into the United States ACME's 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. An Order declaring this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and awarding Amgen its 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/ Jack B. Blumenfeld

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