IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No. _____
BARR LABORATORIES, INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Amgen Inc. ("Amgen") by way of Complaint against Defendant Barr Laboratories, Inc. ("Barr"), 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, Barr is a Delaware corporation having a principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey.

3. Upon information and belief, Barr is a pharmaceutical company engaged in the development, manufacture, sale and marketing of generic pharmaceuticals for sale and use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

4. This is a civil action for infringement of U.S. Patent No. 9,375,405 (the "'405 patent") under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, including §§

271(e)(2), 271(a), 271(b), and 271(c), and for a declaratory judgment of infringement of the '405 patent under 28 U.S.C. §§ 2201 and 2202. This action arises out of Barr's filing of an Abbreviated New Drug Application ("ANDA") No. 090476 seeking approval to manufacture, use and/or sell cinacalcet hydrochloride tablets (EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base) ("Barr's ANDA products").

JURISDICTION AND VENUE

5. 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.

6. This court has personal jurisdiction over Barr because, *inter alia*, it is a Delaware corporation. Upon information and belief, Barr, directly or indirectly, manufactures, imports, markets, and sells generic drugs throughout the United States, including Delaware, and derives substantial revenue from the use or consumption of Barr's products in the State of Delaware. Upon information and belief, Barr maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, Corporate Creations Network Inc., located at 3411 Silverside Road, Tatnall Building Ste. 104, Wilmington, DE 19810. In addition, Barr has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of Delaware courts through the assertions of counterclaims in suits brought in Delaware. *See, e.g., The Brigham and Women's Hospital, Inc. et al. v. Teva Pharms. USA Inc. et al.*, 08-cv-464-HB; *Endo Pharmaceuticals Inc. et al. v. Teva Pharms. USA, Inc. et al.*, C.A. No. 14-1389-RGA.

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

THE PATENT-IN-SUIT

8. 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”).

9. The ’405 patent is assigned to Amgen and Amgen is the owner of the ’405 patent.

10. Amgen is the holder of 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.

11. 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®.

12. The ’405 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) for NDA No. 21-688.

13. The claims of the ’405 patent are directed to pharmaceutical compositions comprising cinacalcet hydrochloride.

BACKGROUND ON SENSIPAR®

14. 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.

15. 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.

16. 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®.

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

18. 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.

19. For SENSIPAR®, the Orange Book lists U.S. Patent Nos. 6,011,068 ("the '068 patent"), 6,031,003 ("the '003 patent"), 6,313,146 ("the '146 patent"), and previously listed U.S. Patent No. 6,211,244 ("the '244 patent") (collectively, "Earlier Listed Patents").

20. The Orange Book also lists, more recently, the '405 patent and its parent, U.S. Patent No. 7,829,595.

ACTS GIVING RISE TO THIS ACTION FOR INFRINGEMENT OF THE PATENT-IN-SUIT

21. Upon information and belief, Barr actively reviews pharmaceutical patents and seeks opportunities to challenge those patents.

22. Barr 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®.

23. On June 16, 2008, Amgen received a letter dated June 13, 2008 from Barr notifying Amgen that Barr had filed ANDA No. 090476 with the FDA under section 505(j) of the Food, Drug and Cosmetics Act ("FDCA") seeking approval to commercially manufacture, use, sell, and/or import Barr's ANDA products. ANDA No. 090476 seeks FDA approval to market Barr's ANDA products prior to the expiration of the Earlier Listed Patents. The stated purpose of Barr's June 13, 2008 letter was to notify Amgen that ANDA No. 090476 included a certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV) ("Paragraph IV Certification") alleging that the claims of the Earlier Listed Patents were invalid or would not be infringed by the commercial manufacture, use, sale, offer for sale, and/or import of Barr's ANDA products.

24. In a separate action, *The Brigham and Women's Hospital, Inc. et al. v. Teva Pharms USA Inc. et al.*, 08-cv-00464 (D. Del.), Amgen asserted the Earlier Listed Patents against Barr. Barr was found to have infringed the asserted claims and the asserted claims were held not invalid and not unenforceable. The latest expiration date of the Earlier Listed Patents is March 8, 2018, on which Amgen's '068 patent expires.

25. On May 13, 2010, Barr received tentative approval from the FDA for ANDA No. 090476.

26. The '405 patent had not issued at the time Barr submitted the above-mentioned Paragraph IV Certification under § 505(j)(2)(A)(vii)(IV) of the FDCA.

27. Barr has not sent Amgen a notice of Paragraph IV Certification alleging 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 Barr’s ANDA products.

28. However, upon information and belief, Barr is aware of the ’405 patent, and has been aware of the ’405 patent for at least several months.

29. The ’405 patent was submitted for Orange Book listing on July 22, 2016, within thirty days of issuance. Upon information and belief, Barr would have become aware of the ’405 patent upon its listing in the Orange Book on or around July 22, 2016.

30. On or about September 12, 2017, the Associate General Counsel of U.S. Intellectual Property Litigation for Teva spoke with counsel for Amgen regarding the ’405 patent and the status of Paragraph IV Certifications for Barr’s ANDA No. 090476. Therefore, upon information and belief, Barr had notice of the existence of the ’405 patent at least as of September 12, 2017.

31. Upon information and belief, Barr intends to launch its ANDA products on or shortly after March 8, 2018. In a separate action regarding pediatric exclusivity of Amgen’s SENSIPAR® product, *Amgen Inc. v. Price et al.*, 17-cv-01006-RDM (D.D.C), Barr filed a motion to intervene as defendant on August 14, 2017. In the motion (D.I. 26), Barr noted that the “FDA has already granted tentative approval for Teva and Barr to market generic versions of Sensipar®, but final approval is contingent on the expiration of Amgen’s patents.” Upon information and belief, based on the intervention, Barr still intends to seek final approval and is preparing to launch Barr’s ANDA products as early as March 8, 2018, the expiration date for the ’068 patent. The intervention in *Amgen Inc. v. Price et al*. indicates Barr’s interest in launching Barr’s ANDA products as soon as possible, as a victory for Amgen in that case will

likely result in pediatric exclusivity for SENSIPAR®, and would delay the earliest possible launch date by six months.

32. Upon information and belief, based upon, *inter alia*, Barr's Paragraph IV Certification to the Earlier Listed Patents and its motion to intervene in the *Amgen Inc. v. Price et al.* case, Barr is seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Barr's ANDA products prior to the expiration of the '405 patent.

33. Pursuant to 21 U.S.C. § 355(j) and 21 C.F.R. § 314.94, Barr is required to make a patent certification under 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV) to each of the Orange Book listed patents, including the '405 patent. Upon information and belief, Barr is aware of the '405 patent and will file such a certification with the FDA on or before March 8, 2018.

FIRST CLAIM FOR RELIEF

34. Amgen incorporates and realleges paragraphs 1-33 above, as if set forth specifically here.

35. Barr submitted ANDA No. 090476 to the FDA to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Barr ANDA products throughout the United States, including Delaware, prior to patent expiry. By submitting the application, Barr committed an act of infringement with respect to the '405 patent, under 35 U.S.C. § 271(e)(2)(A).

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

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

SECOND CLAIM FOR RELIEF

38. Amgen incorporates and realleges paragraphs 1-37 above, as if set forth specifically here.

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

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

41. Barr's actions, including but not limited to filing, maintaining, and not withdrawing ANDA No. 090476 containing Paragraph IV Certifications to the Earlier Listed Patents indicate a refusal to change its course of action in the face of acts by Amgen, including but not limited to Amgen's timely listing of the '405 patent in the Orange Book.

42. Upon information and belief, the manufacture, use, sale, offer for sale, and importation of Barr'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).

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 Barr'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 Barr’s submissions of ANDA No. 090476 under 35 U.S.C. § 271 (e)(2)(A), and that the commercial manufacture, use, offer for sale, sale, and/or importation of Barr’s ANDA products prior to the expiration of the ’405 patent will constitute an act of infringement of 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. 090476 shall be a date that is not earlier than the expiration date of the ’405 patent, inclusive of any extensions.

C. An injunction under 35 U.S.C. § 271 (e)(4)(B) permanently enjoining Barr, its affiliates, subsidiaries, and each of their officers, agents, servants, employees, and those acting or attempting to act in concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of Barr’s ANDA products, within (or into) the United States, 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. A declaration under 28 U.S.C. § 2201 that if Barr, its affiliates, subsidiaries, and each of their officers, agents, servants, employees, and those acting or attempting to act in concert or participation with them or acting on their behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Barr’s ANDA products prior to patent expiry, it will constitute an act of infringement of the ’405 patent;

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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