IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No. _____
DR. REDDY'S LABORATORIES, LTD. and	)	
DR. REDDY'S LABORATORIES, INC.,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Amgen Inc. (Amgen) by way of Complaint against Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (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, Defendant Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") is an Indian corporation, having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500 034, India.

3. Upon information and belief, Defendant Dr. Reddy's Laboratories, Inc. ("DRL Inc.") is a New Jersey corporation, having a principal place of business at 107 College Road East, Princeton, NJ 08540.

4. Upon information and belief, DRL Inc. is a wholly owned subsidiary of DRL Ltd., and is controlled and/or dominated by DRL Ltd.

5. Upon information and belief, DRL Ltd. and DRL Inc. regularly transact business within Delaware, including but not limited to, through DRL Ltd.'s direction of the operations and management of DRL Inc., as well as shipping generic drugs to DRL Inc. from locations outside the United States for marketing, sale and distribution by DRL Inc. 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 DRL Ltd's filing of an Abbreviated New Drug Application ("ANDA") No. 208368 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 DRL Ltd. and DRL Inc. because, *inter alia*, upon information and belief, DRL Ltd. and DRL Inc. 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, DRL Ltd. and DRL Inc. USA acted in concert to file ANDA No. 208368 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, DRL Ltd. and DRL Inc., 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. 208368, 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 DRL Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met. This Court has jurisdiction over DRL Ltd. because, *inter alia*, this action arises from actions of DRL Ltd. directed toward Delaware, and because DRL Ltd. 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, DRL Ltd. 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, DRL Ltd. 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., Galderma Laboratories, LP et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, Civil Action No. 15-670 (D. Del.); *Cephalon, Inc. v. Dr. Reddy's Laboratories, Ltd. et al.*, Civil Action No. 14-1241 (D. Del.). Upon information and belief, Defendants have previously submitted to the jurisdiction of this Court and have availed themselves of the legal protections of the State of Delaware by having filed suit in this jurisdiction. *See, Dr. Reddy's Laboratories, Inc. et al. v. Fresenius Kabi USA, LLC*, Civil Action No. 15-714 (D. Del.).

12. In *Galderma Laboratories, LP et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, Civil Action No. 15-670, D.I. 13 at ¶ 10 (D. Del.), Defendants admitted that this Court has personal jurisdiction over DRL Inc.

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

THE PATENT-IN-SUIT

14. 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.

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

16. 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.

17. 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®.

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

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

BACKGROUND ON SENSIPAR®

20. 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.

21. 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.

22. 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®.

23. 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.

24. 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

25. 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®.

26. Upon information and belief, Defendants collaborated in the research, development, preparation, and filing of ANDA No. 208368 for generic cinacalcet hydrochloride tablets EQ 30 mg, EQ 60 mg, and EQ 90 mg.

27. On August 30, 2016, Amgen received a letter dated August 29, 2016, from DRL Inc. notifying Amgen that DRL Ltd. had filed ANDA No. 208368 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.

28. The stated purpose of DRL Inc.'s August 29, 2016 letter was to notify Amgen that ANDA No. 208368 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 August 29, 2016, letter was a "Detailed Statement" of the factual and legal basis for DRL Ltd.'s Paragraph IV Certification.

29. Upon information and belief, Defendants were aware of the '405 patent when DRL Inc. notified Amgen of its Paragraph IV Certification of the '405 patent.

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

FIRST CLAIM FOR RELIEF

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

32. Upon information and belief, DRL Ltd. filed ANDA No. 208368 with the FDA under the provisions of 21 U.S.C. § 355(j).

33. Upon information and belief, DRL Ltd's ANDA No. 208368 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.

34. On or about August 30, 2016, Amgen received a letter from DRL Inc. dated August 29, 2016, purporting to be a Notice of Certification for ANDA No. 208368 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).

35. DRL Inc.'s letter alleges that the active ingredient in Defendants' ANDA products for which it seeks approval is cinacalcet hydrochloride.

36. Upon information and belief, DRL Ltd. 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.

37. Defendants' submission of ANDA No. 208368 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).

38. 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.

39. 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

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

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

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

43. 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).

44. 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.

45. 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. 208368, 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. 208368 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

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