IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UCB, Inc., and UCB Pharma S.A.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
	)	
InvaGen Pharmaceuticals, Inc.,	)	Civil Action No. 2:15-cv-6919
	)	
Defendant.	)	
	)	

COMPLAINT

Plaintiffs UCB, Inc., and UCB Pharma S.A. (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendant InvaGen Pharmaceuticals, Inc. ("InvaGen") herein allege:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from InvaGen's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of the pharmaceutical product Zyrtec-D® (the "Accused Product") prior to the expiration of United States Patent Nos. 6,469,009 ("the '009 patent"), 7,014,867 ("the '867 patent"), 7,226,614 ("the '614 patent,") (collectively, "the Patents-in-Suit"), which cover Zyrtec-D® or its use.

THE PARTIES

2. Plaintiff UCB, Inc., is a corporation organized and existing under the laws of the State of Delaware, located at 1950 Lake Park Drive, Smyrna, GA 30080. UCB, Inc., is a licensee of the Patents-in-Suit and the beneficial licensor of McNeil Consumer Healthcare, a division of McNeil-PPC, Inc. ("McNeil"), which markets and sells Zyrtec-D® in the United States.

3. Plaintiff UCB Pharma S.A., is a corporation organized under the laws of Belgium, with its principal place of business in Brussels, Belgium. UCB Pharma S.A., is the assignee and owner of the Patents-in-Suit.

4. On information and belief, InvaGen Pharmaceuticals Inc., is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 7 Oser Avenue, Hauppauge, New York 11788. InvaGen has previously submitted to jurisdiction in, and has availed itself of the jurisdiction of this Court by asserting claims in lawsuits filed in this District.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over InvaGen by virtue of, inter alia, its domicile in New York, its intent to market the Accused Product in New York, and its nature as being "at home" in the State of New York.

7. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b)(1) and/or 1400(b).

THE PATENTS-IN-SUIT

8. On October 22, 2002, the United States Patent and Trademark Office issued the '009 patent, entitled "Pharmaceutical Compositions for the Treatment of Rhinitis." At the time of its issue, the '009 patent was assigned to UCB S.A., Belgium, and it was subsequently assigned to UCB Pharma S.A. UCB Pharma S.A. currently holds title to the '009 patent. A copy of the '009 patent is attached hereto as **Exhibit A**.

9. On March 21, 2006, the United States Patent and Trademark Office issued the '867 patent, entitled "Tablet Comprising Cetirizine and Pseudoephedrine." At the time of its issue, the '867 patent was assigned to UCB Farchim S.A., Switzerland, and it was subsequently assigned to UCB Pharma S.A. UCB Pharma S.A. currently holds title to the '867 patent. A copy of the '867 patent is attached hereto as **Exhibit B**.

10. On June 5, 2007, the United States Patent and Trademark Office issued the '614 patent, entitled "Tablet Comprising Cetirizine and Pseudoephedrine." At the time of its issue, the '614 patent was assigned to UCB Farchim S.A., Switzerland, and it was subsequently assigned to UCB Pharma S.A. UCB Pharma S.A. currently holds title to the '614 patent. A copy of the '614 patent is attached hereto as **Exhibit C**.

ZYRTEC-D®

11. McNeil is a licensee of the Patents-in-Suit and holds the approved New Drug Application No. 021150 ("the Zyrtec-D® NDA") for cetirizine HCl 5 mg/ pseudoephedrine HCl 120 mg tablets, which are sold by McNeil in the United States, including in this District, under the trade name Zyrtec-D®.

12. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the Patents-in-Suit are listed in the FDA publication, "Approved Drug Products with Therapeutic

Equivalence Evaluations" (the "Orange Book"), with respect to Zyrtec-D®.

INVAGEN'S ANDA

13. On information and belief, InvaGen submitted ANDA No. 207392 ("the InvaGen ANDA") to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval to market cetirizine HCl 5 mg/pseudoephedrine HCl 120 mg tablets, *i.e.*, the Accused Product.

14. The InvaGen ANDA refers to and relies upon the Zyrtec-D® NDA and contains data which, according to InvaGen, demonstrate the bioequivalence of the Accused Product and Zyrtec-D®.

15. On October 21, 2015, Plaintiff UCB Pharma S.A., received from InvaGen a letter and attached memoranda (the "InvaGen Notification"), wherein InvaGen disclosed that the InvaGen ANDA includes a certification, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the Patents-in-Suit are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the Accused Product ("the Paragraph IV Certification").

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,469,009

16. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-15 of this Complaint.

17. InvaGen has infringed the '009 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the InvaGen ANDA, by which InvaGen seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation into the United States of the Accused Product prior to the expiration of the '009 patent.

18. InvaGen's commercial manufacture, use, offer to sell, or sale of the InvaGen Products within the United States, or importation of the Accused Products into the

United States during the term of the ’009 patent would further infringe the ’009 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

19. Plaintiffs will be substantially and irreparably harmed if InvaGen is not enjoined from infringing the ’009 patent.

20. Plaintiffs have no adequate remedy at law.

21. This case is an exceptional one, and Plaintiffs are entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 7,014,867

22. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-15 of this Complaint.

23. InvaGen has infringed the ’867 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the InvaGen ANDA, by which InvaGen seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation into the United States of the Accused Product prior to the expiration of the ’867 patent.

24. InvaGen’s commercial manufacture, use, offer to sell, or sale of the Accused Product within the United States, or importation of the Accused Product into the United States during the term of the ’867 patent would further infringe the ’867 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

25. Plaintiffs will be substantially and irreparably harmed if InvaGen is not enjoined from infringing the ’867 patent.

26. Plaintiffs have no adequate remedy at law.

27. This case is an exceptional one, and Plaintiffs are entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 7,226,614

28. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-15 of this Complaint.

29. InvaGen has infringed the '614 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the InvaGen ANDA, by which InvaGen seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation into the United States of the Accused Product prior to the expiration of the '614 patent.

30. InvaGen's commercial manufacture, use, offer to sell, or sale of the Accused Product within the United States, or importation of the Accused Product into the United States during the term of the '614 patent would further infringe the '614 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

31. Plaintiffs will be substantially and irreparably harmed if InvaGen is not enjoined from infringing the '614 patent.

32. Plaintiffs have no adequate remedy at law.

33. This case is an exceptional one, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, UCB, Inc., and UCB Pharma S.A., pray for a judgment in their favor and against Defendant InvaGen Pharmaceuticals, Inc., and respectfully request the following relief:

A. A judgment declaring that InvaGen has infringed U.S. Patent No. 6,469,009;

B. A judgment declaring that InvaGen has infringed U.S. Patent No. 7,014,867;

C. A judgment declaring that InvaGen has infringed U.S. Patent No. 7,226,614;

D. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining InvaGen, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling the Accused Product within the United States, or importing the Accused Product into the United States, prior to the expiration date of the '009, '867, and '614 patents;

E. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 207392, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the '009, '867, and '614 patents, including any extensions;

F. If InvaGen commercially manufactures, uses, offers to sell, or sells the Accused Product within the United States, or imports the Accused Product into the United States, prior to the expiration of the '009, '867, and '614 patents, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

G. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

H. Costs and expenses in this action; and

I. Such other relief as the Court deems just and proper.

Respectfully submitted,

/s/ James S. Trainor

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