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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

CADENCE PHARMACEUTICALS, INC. and SCR PHARMATOP,

Plaintiffs,

v.

SANDOZ INC.,

Defendant.

CASE NO. '13CV0278 JAH BLM

COMPLAINT FOR PATENT INFRINGEMENT

COMPLAINT

Plaintiffs Cadence Pharmaceuticals, Inc. and SCR Pharmatop (collectively, "Plaintiffs") for their Complaint against defendant Sandoz Inc. ("Sandoz"), allege as follows:

PARTIES

1. Plaintiff Cadence Pharmaceuticals, Inc. ("Cadence") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 12481 High Bluff Drive, Suite 200, San Diego, California, 92130. As set forth herein, Cadence is the exclusive licensee of the Patents-in-Suit.

2. Plaintiff SCR Pharmatop ("Pharmatop") is a civil law partnership organized and existing under the laws of France, having its headquarters at 10, Square St. Florentin, 78150 Le Chesnay, France. As set forth herein, Pharmatop is the assignee of the Patents-in-Suit.

3. Upon information and belief, defendant Sandoz is a company organized and existing under the laws of Colorado, having a principal place of business at 506 Carnegie Center, Princeton, New Jersey 08450. Upon information and belief, Sandoz is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, and Sandoz regularly conducts business in California including in this judicial district.

NATURE OF THE ACTION

4. This is a civil action for infringement of United States Patent No. 6,028,222 and U.S. Patent No. 6,992,218 (collectively, the "Patents-in-Suit"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100 e*t seq*.

JURISDICTION AND VENUE

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

6. This Court has personal jurisdiction over Sandoz because, *inter alia*, Sandoz has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of a tortious act of patent infringement that has led to foreseeable harm and injury to Cadence, a company with its principal place of business in this forum. In addition, this Court has personal jurisdiction over Sandoz for the further reason that Sandoz maintains continuous and systematic business contacts with the state of California that include the sale of pharmaceutical products in California. Upon information and belief, Sandoz derives substantial revenue from the sale of those products in California and has availed itself of the privilege of conducting business within the State of California.

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

THE PATENTS-IN-SUIT

8. United States Patent No. 6,028,222 ("the '222 patent"), titled "Stable Liquid Paracetamol Compositions, and Method for Preparing the Same," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on February 22, 2000, to Pharmatop, the assignee of the named inventors. Pharmatop has been, and continues to be, the sole assignee of the '222 patent.

9. Pharmatop granted an exclusive license to the '222 patent to Bristol-Myers Squibb Company ("BMS"), with a right to sublicense. BMS in turn granted Cadence an exclusive sublicense, exclusive even to itself, to the '222 patent with regard to all rights pertinent to this action. A true and correct copy of the '222 patent is attached as Exhibit A.

10. United States Patent No. 6,992,218 ("the '218 patent"), titled "Method for Obtaining Aqueous Formulations of Oxidation-Sensitive Active Principles," was duly and legally issued by the PTO on January 31, 2006, to Pharmatop, the assignee of the named inventors. Pharmatop has been, and continues to be, the sole assignee of the '218 patent.

11. Pharmatop granted an exclusive license to the '218 patent to BMS, with a right to sublicense. BMS in turn granted Cadence an exclusive sublicense, exclusive even to itself, to the '218 patent with regard to all rights pertinent to this action. A true and correct copy of the '218 patent is attached as Exhibit B.

OFIRMEV®

12. Cadence holds approved New Drug Application ("NDA") No. 022450 for OFIRMEV®, the first and only intravenous (IV) formulation of acetaminophen available in the United States. OFIRMEV® was approved by the Food and Drug Administration (the "FDA") on November 2, 2010. OFIRMEV® is indicated for the treatment of mild to moderate pain, management of moderate to severe pain with adjunctive opioid analgesics, and reduction of fever.

13. The publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '222 patent and the '218 patent were listed in the Orange Book with respect to OFIRMEV®.

SANDOZ'S INFRINGEMENT OF THE PATENTS-IN-SUIT

14. Upon information and belief, Sandoz submitted Abbreviated New Drug Application ("ANDA") No. 20-4052 to the FDA, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of Acetaminophen Injection, 10 mg/mL, 100 mL vials ("Sandoz's Generic Product"), as a generic version of the OFIRMEV® product, prior to the expiration of the Patents-in-Suit.

15. By a letter dated December 21, 2012 (the "Sandoz Letter"), which was received by outside counsel on December 24, 2012, Sandoz stated that it had submitted ANDA No. 20-4052 seeking approval to engage in the commercial

manufacture, use, sale or offer for sale, and/or importation of Sandoz's Generic Product prior to the expiration of the Patents-in-Suit.

16. The Sandoz Letter also stated that ANDA No. 20-4052 contains a "Paragraph IV certification" that alleges the '222 patent and '218 patent are invalid, unenforceable, and that Sandoz's Generic Product purportedly will not infringe any valid claim of the '222 patent and the '218 patent.

17. Upon information and belief, Sandoz has represented to the FDA that Sandoz's Generic Product will have the same active ingredient as OFIRMEV®, have the same route of administration, dosage form, and strength as OFIRMEV®, and is bioequivalent to OFIRMEV®.

18. Sandoz's submission of ANDA No. 20-4052 to the FDA, including its section 355(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the Patents-in-Suit under 35 USC § 271(e)(2)(A). Moreover, in the event that Sandoz commercially manufactures, imports, uses, offers for sale, or sells Sandoz's Generic Product or induces or contributes to such conduct, said actions would constitute infringement of the Patents-in-Suit under 35 USC § 271(a), (b) and/or (c).

19. Sandoz was aware of the Patents-in-Suit prior to filing ANDA No. 20-4052, and its actions render this an exceptional case under 35 U.S.C. § 285.

20. The acts of infringement by Sandoz set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

COUNT I

(Infringement of the '222 Patent by Sandoz)

21. Plaintiffs incorporate each of the preceding paragraphs 1 to 20 as if fully set forth herein.

22. Sandoz's submission of ANDA No. 20-4052, including its § 355(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '222 patent pursuant to 35 U.S.C. § 271(e)(2) by Sandoz.

23. Upon FDA approval of ANDA No. 20-4052, Sandoz will infringe the '222 patent by making, using, offering to sell, or selling Sandoz's Generic Product in the United States and/or importing Sandoz's Generic Product into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a), (b) and/or (c).

24. Upon information and belief, Sandoz had actual and constructive knowledge of the '222 patent prior to filing ANDA No. 20-4052 and acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '222 patent.

COUNT II

(Declaratory Judgment of Infringement of the '222 Patent by Sandoz)

25. Plaintiffs incorporate each of the preceding paragraphs 1 to 20 as if fully set forth herein.

26. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

27. Plaintiffs are further entitled to a declaration that, if Sandoz, prior to patent expiry, commercially manufactures, uses, offers for sale, or sells Sandoz's Generic Product within the United States, imports Sandoz's Generic Product into the United States, or induces or contributes to such conduct, Sandoz would infringe the '222 patent under 35 U.S.C. § 271(a), (b) and/or (c).

28. Plaintiffs will be irreparably harmed by Sandoz's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT III

(Infringement of the '218 Patent by Sandoz)

29. Plaintiffs incorporate each of the preceding paragraphs 1 to 20 as if fully set forth herein.

30. Sandoz's submission of ANDA No. 20-4052, including its section 355(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '218 patent pursuant to 35 U.S.C. § 271(e)(2) by Sandoz.

31. Upon information and belief, upon FDA approval of ANDA No. 20-4052, Sandoz will infringe the '218 patent by making, using, offering to sell, or selling Sandoz's Generic Product in the United States and/or importing Sandoz's Generic Product into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a), (b) and/or (c).

32. Upon information and belief, Sandoz had actual and constructive knowledge of the '218 patent prior to filing ANDA No. 20-4052 and acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '218 patent.

COUNT IV

(Declaratory Judgment of Infringement of the '218 Patent by Sandoz)

33. Plaintiffs incorporate each of the preceding paragraphs 1 to 20 as if fully set forth herein.

34. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

35. Plaintiffs are further entitled to a declaration that, if Sandoz, prior to patent expiry, commercially manufactures, uses, offers for sale, or sells Sandoz's Generic Product within the United States, imports Sandoz's Generic Product into the United States, or induces or contributes to such conduct, Sandoz would infringe the '218 patent under 35 U.S.C. § 271(a), (b) and/or (c).

36. Plaintiffs will be irreparably harmed by Sandoz's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Sandoz infringed each of the Patents-In-Suit;

B. An order issued pursuant to 35 U.S.C. § 271(e)(4)(a) that the effective date of any approval of Sandoz's ANDA No. 20-4052 shall not be earlier than the expiration dates of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

C. A preliminary and permanent injunction restraining and enjoining Sandoz and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States of any of Sandoz's Generic Product until the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

D. That Plaintiffs be awarded monetary relief if Sandoz commercially manufactures, uses, offers for sale, or sells its generic version of Cadence's OFIRMEV® brand product, or any other product that infringes or induces or contributes to the infringement of the Patents-in-Suit, within the United States before the latest expiration date of any of the Patents-In-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

E. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

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F. An award of costs and expenses in this action; and

G. Such other and further relief as the Court may deem just and proper.

Dated: February 4, 2013

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