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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

CADENCE PHARMACEUTICALS, INC., SCR PHARMATOP & MALLINCKRODT IP, Plaintiffs, v. FRESENIUS KABI USA, LLC, Defendant. AND RELATED COUNTERCLAIMS	CASE NO. 13-CV-00139 DMS (MDD) **AMENDED COMPLAINT FOR PATENT INFRINGEMENT** **Judge: Hon. Dana M. Sabraw**

COMPLAINT

Plaintiffs Cadence Pharmaceuticals, Inc., SCR Pharmatop, and Mallinckrodt IP (collectively, "Plaintiffs") for their Complaint against defendant Fresenius Kabi USA, LLC ("Fresenius"), 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. Plaintiff Mallinckrodt IP is a company organized and existing under the laws of Ireland, having a registered address of Damastown Industrial Estate, Mulhuddart, Dublin 15, Ireland.

4. Upon information and belief, defendant Fresenius is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois, 60173. Upon information and belief, Fresenius is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, including in this judicial district.

NATURE OF THE ACTION

5. 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

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

7. This Court has personal jurisdiction over Fresenius because, *inter alia*, Fresenius 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. This Court has personal jurisdiction over Fresenius for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

8. This Court has personal jurisdiction over Fresenius because, *inter alia*, Fresenius has purposefully availed itself of the rights and benefits of California law by engaging in systematic and continuous contacts with California.

9. Upon information and belief, Fresenius regularly and continuously transacts business within the State of California, including by selling pharmaceutical products in California. Upon information and belief, Fresenius 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.

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

THE PATENTS-IN-SUIT

11. 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.

12. 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.

13. 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.

14. 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.

15. As part of the corporate restructuring resulting from the purchase of Cadence by Mallinckrodt plc, Mallinckrodt IP is contemplated to become the exclusive sub-licensee to the '218 and '222 Patents.

OFIRMEV®

16. 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. As part of the corporate restructuring resulting from the purchase of Cadence by Mallinckrodt plc, Mallinckrodt IP is contemplated to become the holder of NDA No. 022450.

17. 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.

18. 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®.

FRESENIUS'S INFRINGEMENT OF THE PATENTS-IN-SUIT

19. Upon information and belief, Fresenius submitted New Drug Application ("NDA") No. 20-4767 to the FDA, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)), 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 ("Fresenius's Generic Product"), as a generic version of the OFIRMEV® product, prior to the expiration of the Patents-in-Suit.

20. By a letter dated December 5, 2012 (the "Fresenius Letter"), Fresenius stated that it had submitted NDA No. 20-4767 seeking approval to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of Fresenius's Generic Product prior to the expiration of the Patents-in-Suit.

21. The Fresenius Letter also stated that NDA No. 20-4767 contains a "Paragraph IV certification" that alleges the '222 patent and '218 patent are invalid, unenforceable, and that Fresenius's Generic Product purportedly will not infringe any valid claim of the '222 patent and the '218 patent.

22. Upon information and belief, Fresenius has represented to the FDA that Fresenius'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®.

23. Fresenius's submission of NDA No. 20-4767 to the FDA, including its section 355(b)(2)(A)(iv) allegations, constitutes infringement of the Patents-in-Suit under 35 USC § 271(e)(2)(A). Moreover, in the event that Fresenius commercially manufactures, imports, uses, offers for sale, or sells Fresenius'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).

24. Fresenius was aware of the Patents-in-Suit prior to filing NDA No. 20-4767, and its actions render this an exceptional case under 35 U.S.C. § 285.

25. The acts of infringement by the Fresenius 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 Fresenius)

26. Plaintiffs incorporate each of the preceding paragraphs 1 to 22 as if fully
set forth herein.

27. Fresenius's submission of NDA No. 20-4767, including its § 355(b)(2)(A)(iv) allegations, constitutes infringement of the '222 patent pursuant to 35 U.S.C. § 271(e)(2) by Fresenius.

28. On information and belief, upon FDA approval of NDA No. 20-4767, Fresenius will infringe the '222 patent by making, using, offering to sell, or selling Fresenius's Generic Product in the United States and/or importing Fresenius'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).

29. Upon information and belief, Fresenius had actual and constructive knowledge of the '222 patent prior to filing NDA No. 20-4767 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 Fresenius)

30. Plaintiffs incorporate each of the preceding paragraphs 1 to 22 as if fully set forth herein.

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

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

33. Plaintiffs will be irreparably harmed by Fresenius'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 Fresenius)

34. Plaintiffs incorporate each of the preceding paragraphs 1 to 22 as if fully
set forth herein.

35. Fresenius's submission of NDA No. 20-4767, including its section 355(b)(2)(A)(iv) allegations, constitutes infringement of the '218 patent pursuant to 35 U.S.C. § 271(e)(2) by Fresenius.

36. On information and belief, upon FDA approval of NDA No. 20-4767, Fresenius will infringe the '218 patent by making, using, offering to sell, or selling Fresenius's Generic Product in the United States and/or importing Fresenius'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).

37. Upon information and belief, Fresenius had actual and constructive knowledge of the '218 patent prior to filing NDA No. 20-4767 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 Fresenius)

38. Plaintiffs incorporate each of the preceding paragraphs 1 to 22 as if fully set forth herein.

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

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

41. Plaintiffs will be irreparably harmed by Fresenius'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 Fresenius infringed each of the Patents-In-Suit;

B. An order issued pursuant to 35 U.S.C. § 271(e)(4) that the effective date of any approval of Fresenius's NDA No. 20-4767 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 Fresenius 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 Fresenius'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 Fresenius 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;

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: August 6, 2014

LATHAM & WATKINS LLP

By: s/ Stephen P. Swinton
Stephen P. Swinton
Darryl H. Steensma

Attorneys for Plaintiffs
CADENCE PHARMACEUTICALS, INC. AND MALLINCKRODT IP

SCHWARTZ SEMERDJIAN BALLARD & CAULEY LLP

By: s/John S. Moot (w/permission)
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Attorneys for Plaintiff
SCR PHARMATOP

PROOF OF SERVICE

I am employed in the County of San Diego, State of California. I am over the age of 18 years and not a party to this action. My business address is Latham & Watkins LLP, 12670 High Bluff Drive, San Diego, CA 92130.

On August 6, 2014, I served the following document described as:

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

by serving a true copy of the above-described document in the following manner:

BY ELECTRONIC FILING

I am familiar with the United States District Court, Southern District of California's practice for collecting and processing electronic filings. Under that practice, documents are electronically filed with the court. The court's CM/ECF system will generate a Notice of Electronic Filing (NEF) to the filing party, the assigned judge, and any registered users in the case. The NEF will constitute service of the document. Registration as a CM/ECF user constitutes consent to electronic service through the court's transmission facilities. Under said practice, the following CM/ECF users were served:

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I declare that I am employed in the office of a member of the Bar of, or permitted to practice before, this Court at whose direction the service was made and declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on August 6, 2014, at San Diego, California.

/s/ Stephen P. Swinton