IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CADENCE PHARMACEUTICALS, INC. and SCR PHARMATOP,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
WOCKHARDT LIMITED, WOCKHARDT BIO AG and WOCKHARDT USA LLC,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Cadence Pharmaceuticals, Inc. and SCR Pharmatop (collectively, "Plaintiffs") for their Complaint against defendants Wockhardt Limited, Wockhardt Bio AG, and Wockhardt USA LLC (collectively, "Defendants"), 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 business entity organized and existing under the laws of the Republic 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 Wockhardt Limited is an Indian corporation having a principle place of business at Wockhardt Towers, Bandra Kurla Complex,

Bandra (East) Mumbai – 400 051, Maharashtra, India. Upon information and belief, Wockhardt Limited is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, either on its own or through its affiliates, and Wockhardt Limited regularly conducts business in Delaware including in this judicial district.

4. Upon information and belief, Defendant Wockhardt Bio AG is a Swiss corporation, having a principal place of business at Baarerstrasse 43, 6300 ZUG, Switzerland. Upon information and belief, Wockhardt Bio AG is a subsidiary of Wockhardt Limited. Upon information and belief, Wockhardt Bio AG is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, either on its own or through its affiliates, and Wockhardt Bio AG regularly conducts business in Delaware including in this judicial district.

5. Upon information and belief, Defendant Wockhardt USA LLC is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 20 Waterview Boulevard, 3rd Floor, Parsippany, NJ 07054-1271. Upon information and belief, Wockhardt USA LLC is a subsidiary of Wockhardt Limited. Upon information and belief, Wockhardt USA LLC is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, and Wockhardt USA LLC regularly conducts business in Delaware including in this judicial district.

NATURE OF THE ACTION

6. This is a civil action for infringement of United States Patent Nos. 6,028,222 and 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 *et seq*.

JURISDICTION AND VENUE

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

8. This Court has personal jurisdiction over Defendant Wockhardt USA LLC by virtue of, *inter alia*, Wockhardt USA LLC's organization under the laws of the State of Delaware.

9. This Court has personal jurisdiction over Defendant Wockhardt Limited and Wockhardt Bio AG because, together with Wockhardt USA LLC, Wockhardt Limited and Wockhardt Bio AG have committed, or aided, abetted, actively induced, contributed to, or participated in the commission of a tortious act of patent infringement as further detailed herein through the filing with the United States Food and Drug Administration (the "FDA") of Abbreviated New Drug Application ("ANDA") No. 205746 containing a "Paragraph IV Certification" seeking approval to engage in the commercial manufacture, use, sale, or offer for sale, and/or importation of a drug product prior to expiration of the Patents-in-Suit that has led to foreseeable harm and injury to Cadence, a Delaware corporation. This Court has personal jurisdiction over Wockhardt Limited and Wockhardt Bio AG for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

10. This Court has personal jurisdiction over Defendant Wockhardt Limited because, *inter alia*, Wockhardt Limited has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware.

11. Upon information and belief, Defendant Wockhardt Limited 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, including Wockhardt USA LLC.

Upon information and belief, Wockhardt Limited 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.

12. In addition, Defendant Wockhardt Limited has previously consented to jurisdiction in this forum for the purpose of litigating patent disputes, and has purposely availed itself of this forum by asserting counterclaims, in at least the following actions:

- *Avanir Pharmaceuticals, Inc. v. Wockhardt, Ltd. and Wockhardt USA LLC*, Case No. 12-cv-01125-LPS, (D. Del. 2012).
- *Pfizer Inc. et al. v. Wockhardt, LTD and Wockhardt USA, LLC*, Case No. 12-817 SLR, (consolidated with Case No. 12-808 SLR) (D. Del. 2012).
- *Pfizer Inc. Warner-Lambert Company LLC et al. v. Wockhardt Limited and Wockhardt USA, LLC*, Case No. 09-312-GMS, (D. Del. 2009)

13. This Court has personal jurisdiction over Defendant Wockhardt Bio AG because, *inter alia*, Wockhardt Bio AG has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware.

14. Upon information and belief, Defendant Wockhardt Bio AG 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, including Wockhardt USA LLC. Upon information and belief, Wockhardt Bio AG 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.

15. In addition, Defendant Wockhardt Bio AG has previously consented to jurisdiction in this forum for the purpose of litigating patent disputes, and has purposely availed itself of this forum by asserting counterclaims, in at least the following action: *Pfizer Inc. and*

UCB Pharma GMBH v. Wockhardt Bio AG and Wockhardt USA LLC, Case No. 13-1387-GMS, (D. Del. 2013).

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

THE PATENTS-IN-SUIT

17. 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.

18. 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 hereto. A true and correct copy of the '222 Patent is attached as Exhibit A.

19. 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.

20. 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 hereto. A true and correct copy of the '218 Patent is attached as Exhibit B.

OFIRMEV®

21. 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 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.

22. 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®.

DEFENDANTS' INFRINGEMENT OF THE PATENTS-IN-SUIT

23. Upon information and belief, Defendant Wockhardt Bio AG submitted Abbreviated New Drug Application ("ANDA") No. 205746 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 solution 10 mg/mL ("Wockhardt's Generic Product"), as a generic version of the OFIRMEV® product, prior to the expiration of the Patents-in-Suit.

24. On or about December 13, 2013, outside counsel for Pharmatop received a letter dated December 12, 2013 on letterhead for Defendant Wockhardt USA LLC, and signed by a representative of Defendant Wockhardt Limited and addressed to representatives of Cadence and Pharmatop (the "Wockhardt Letter"). The Wockhardt Letter states that Defendant Wockhardt Bio AG had submitted ANDA No. 205746 seeking approval to engage in the commercial

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

25. The Wockhardt Letter states that ANDA No. 205746 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii) which alleges that claims 1-18 of the '222 Patent are invalid, that Wockhardt's Generic Product does not infringe claims 19-28 of the '222 Patent, that the claims of the '218 Patent are invalid, and that Wockhardt's Generic Product will not infringe claims 2, 5-7, 9,10 or 12-18 of the '218 Patent.

26. By filing ANDA No. 205746, Defendant Wockhardt Bio AG has necessarily represented to the FDA that the components of Wockhardt's Generic Product have the same active ingredient as that of the corresponding components of OFIRMEV®, have the same route of administration, dosage form, and strengths as the corresponding components of OFIRMEV®, and are bioequivalent to the corresponding components of OFIRMEV®.

27. Defendant Wockhardt Bio AG's submission of ANDA No. 205746 to the FDA, including the § 355(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A). Moreover, in the event that Defendants commercially manufacture, import, use, offer for sale, or sell Wockhardt's Generic Product or induce or contribute to such conduct, said actions would constitute infringement of the Patents-in-Suit under 35 USC § 271(a), (b) and/or (c).

28. Defendants Wockhardt Limited, Wockhardt Bio AG, and Wockhardt USA LLC are jointly and severally liable for infringement of the Patents-in Suit. Upon information and belief, Wockhardt Limited, Wockhardt Bio AG, and Wockhardt USA LLC participated in, contributed to, aided, abetted, and/or induced Wockhardt Bio AG's submission of ANDA No. 205746 and its section 355(j)(2)(A)(vii)(IV) allegations to the FDA.

29. Defendants were aware of the Patents-in-Suit prior to filing ANDA No. 205746, and their actions render this an exceptional case under 35 U.S.C. § 285.

30. The acts of infringement by Defendants 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 DEFENDANTS)

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

32. Defendant Wockhardt Bio AG's submission of ANDA No. 205746, 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 Defendants.

33. Upon FDA approval of ANDA No. 205746, Defendants will infringe the '222 Patent by making, using, offering to sell, or selling Wockhardt's Generic Product in the United States and/or importing Wockhardt'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).

34. Upon information and belief, Defendants had actual and constructive knowledge of the '222 Patent prior to filing ANDA No. 205746 and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '222 Patent.

COUNT II
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '222 PATENT BY DEFENDANTS)

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

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

37. Plaintiffs are further entitled to a declaration that, if Defendants, prior to patent expiry, commercially manufacture, use, offer for sale, or sell Wockhardt's Generic Product within the United States, import Wockhardt's Generic Product into the United States, or induce or contribute to such conduct, Defendants would infringe the '222 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

38. Plaintiffs will be irreparably harmed by Defendants' 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 DEFENDANTS)

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

40. Defendant Wockhardt Bio AG's submission of ANDA No. 205746, including the § 355 (j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '218 Patent pursuant to 35 U.S.C. § 271(e)(2) by Defendants.

41. Upon FDA approval of ANDA No. 205746, Defendants will infringe the '218 Patent by making, using, offering to sell, or selling Wockhardt's Generic Product in the United States and/or importing Wockhardt'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).

42. Upon information and belief, Defendants had actual and constructive knowledge of the '218 Patent prior to filing ANDA No. 205746 and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '218 Patent.

COUNT IV
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '218 PATENT BY THE WOCKHARDT DEFENDANTS)

43. Plaintiffs incorporate each of the preceding paragraphs 1 to 42 as if fully set forth herein.

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

45. Plaintiffs are further entitled to a declaration that, if Defendants, prior to patent expiry, commercially manufacture, use, offer for sale, or sell Wockhardt's Generic Product within the United States, import Wockhardt's Generic Product into the United States, or induce or contribute to such conduct, Defendants would infringe the '218 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

46. Plaintiffs will be irreparably harmed by Defendants' 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 all Defendants have infringed each of the Patents-In-Suit;

B. A declaration that if Defendants, prior to patent expiry, commercially manufacture, use, offer for sale, or sell Wockhardt's Generic Product within the United States, import Wockhardt's Generic Product into the United States, or induce or contribute to such conduct, Defendants would infringe the patent-in-suit.

C. An order issued pursuant to 35 U.S.C. § 271(e)(4)(a) that the effective date of any approval of ANDA No. 205746 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;

D. A preliminary and permanent injunction restraining and enjoining Defendants and their 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 Wockhardt'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;

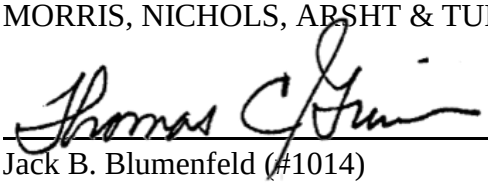
E. That Plaintiffs be awarded monetary relief if Defendants commercially manufacture, use, offer for sale, or sell their respective generic versions of Cadence's OFIRMEV® brand product, or any other product that infringes or induces or contributes to the infringement of the Patents-in-Suit, within the 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;

F. A declaration that this is an exceptional case and an award of its reasonable expenses, including attorneys' fees pursuant to 35 U.S.C. § 285;

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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