IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CADENCE PHARMACEUTICALS, INC., SCR PHARMATOP, and MALLINCKRODT IP, Plaintiffs, v. INNOPHARMA LICENSING LLC and INNOPHARMA, INC., Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Cadence Pharmaceuticals, Inc., SCR Pharmatop, and Mallinckrodt IP (collectively, "Plaintiffs") for their Complaint against defendants InnoPharma Licensing LLC and InnoPharma, Inc. (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 its principal place of business at 675 James S. McDonnell Blvd., Hazelwood, Missouri 63042. Cadence is a wholly-owned subsidiary of Mallinckrodt plc.

2. Plaintiff SCR Pharmatop ("Pharmatop") is a business entity 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 ("Mallinckrodt") is a company organized and existing under the laws of Ireland, having a registered address of Damastown Industrial Estate, Mulhaddart, Dublin 15, Ireland. As set for the herein, Mallinckrodt is currently the exclusive sub-licensee of the Patents-in-Suit.

4. Upon information and belief, Defendant InnoPharma Licensing LLC ("InnoPharma Licensing") is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 10 Knightsbridge Road, Piscataway, New Jersey 08854. Upon Information and belief, InnoPharma Licensing is a wholly-owned subsidiary of InnoPharma, Inc. Upon information and belief, InnoPharma Licensing is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, including in this judicial district. Upon information and belief, InnoPharma Licensing additionally operates as a patent owner or lessor for InnoPharma, Inc.

5. Upon information and belief, Defendant InnoPharma, Inc. ("InnoPharma") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 10 Knightsbridge Road, Piscataway, New Jersey 08854. Upon information and belief, InnoPharma is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, 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 InnoPharma Licensing because, *inter alia*, InnoPharma Licensing is a Delaware company. Additionally, InnoPharma Licensing 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 Delaware corporation. This Court has personal jurisdiction over InnoPharma Licensing for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

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

10. Upon information and belief, InnoPharma Licensing regularly and continuously transacts business within the State of Delaware, including by selling pharmaceutical products in Delaware. Upon information and belief, InnoPharma Licensing 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 personal jurisdiction over InnoPharma because, *inter alia*, InnoPharma is a Delaware company. Additionally, InnoPharma 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 Delaware corporation. This Court has personal jurisdiction over InnoPharma for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

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

13. Upon information and belief, InnoPharma regularly and continuously transacts business within the State of Delaware, including by selling pharmaceutical products in Delaware. Upon information and belief, InnoPharma 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.

14. InnoPharma has admitted that it is subject to this Court's jurisdiction in other actions because "it has conducted and does conduct business within the State of Delaware." *See Cephalon, Inc. v. InnoPharma*, No. 1:13-cv-02081-GMS, D.I. 7 at ¶ 6; *Cephalon, Inc. v. InnoPharma*, No. 1:14-cv-00590-GMS, D.I. 6 at ¶ 6. InnoPharma additionally did not challenge this Court's exercise of personal jurisdiction over it in at least two other cases. *See, e.g., Spectrum Pharms. Inc. v. InnoPharma Inc.*, No. 1:12-cv-00260-RGA; *Cumberland Pharms. Inc. v. InnoPharma Inc.*, No. 1:12-cv-00618-LPS.

15. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b). In addition, this action involves the same two patents that were at issue in the action captioned *Cadence Pharms., Inc., et al. v. Exela Pharma Scis., LLC, et al.*, No. 1:11-cv-00733-LPS (D. Del.), including the Memorandum and Opinion dated November 14, 2013.

THE PATENTS-IN-SUIT

16. 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.

17. 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 sub-license, 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.

18. 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.

19. Pharmatop granted an exclusive license to the ’218 patent to BMS, with a right to sublicense. BMS in turn granted Cadence an exclusive sub-license, 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.

20. As part of the corporate restructuring resulting from the purchase of Cadence by Mallinckrodt plc, Mallinckrodt is currently the exclusive sub-licensee to the ’222 patent and the ’218 patent.

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

22. 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.

23. 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

24. Upon information and belief, InnoPharma Licensing submitted NDA No. 20-6968 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 for injection 10 mg/mL ("InnoPharma's Generic Product"), prior to the expiration of the Patents-in-Suit.

25. By a letter received by Plaintiffs on August 12, 2014 (the "InnoPharma Letter"), InnoPharma Licensing stated that it had submitted NDA No. 20-6968 seeking approval to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of InnoPharma's Generic Product prior to the expiration of the Patents-in-Suit.

26. The InnoPharma Letter also stated that NDA No. 20-6968 contains a "Paragraph IV" certification under 21 U.S.C. § 355(b)(2)(A)(iv) that alleges that the '222 patent and '218 patent are "invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, sale or offer for sale" of InnoPharma's Generic Product.

27. Upon information and belief, InnoPharma Licensing has represented to the FDA that InnoPharma's Generic Product will have the same active ingredient as OFIRMEV®, have

the same route of administration, dosage form, and strength as OFIRMEV®, and be bioequivalent to OFIRMEV®.

28. InnoPharma Licensing's submission of NDA No. 20-6968 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 Defendants commercially manufacture, import, use, offer for sale, or sell InnoPharma'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).

29. InnoPharma Licensing was aware of the Patents-in-Suit prior to filing NDA No. 20-6968, and its actions render this an exceptional case under 35 U.S.C. § 285.

30. On information and belief, InnoPharma Licensing and InnoPharma collaborated and acted in concert in the decision to file and also in the filing of NDA No. 20-6968.

31. 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)

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

33. Defendants' submission of NDA No. 20-6968, including its § 355(b)(2)(A)(iv) allegations, constitutes infringement of the '222 patent pursuant to 35 U.S.C. § 271(e)(2) by Defendants.

34. On information and belief, upon FDA approval of NDA No. 20-6968, Defendants will infringe the '222 patent by making, using, offering to sell, or selling InnoPharma's Generic

Product in the United States and/or importing InnoPharma'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).

35. Upon information and belief, Defendants had actual and constructive knowledge of the '222 patent prior to filing NDA No. 20-6968 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)

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

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

38. Plaintiffs are further entitled to a declaration that, if Defendants, prior to patent expiry, commercially manufacture, use, offer for sale, or sell InnoPharma's Generic Product within the United States, import InnoPharma'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).

39. 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)

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

41. Defendants' submission of NDA No. 20-6968, including the section 355(b)(2)(A)(iv) allegations, constitutes infringement of the '218 patent pursuant to 35 U.S.C. § 271(e)(2) by Defendants.

42. On information and belief, upon FDA approval of NDA No. 20-6968, Defendants will infringe the '218 patent by making, using, offering to sell, or selling InnoPharma's Generic Product in the United States and/or importing InnoPharma'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).

43. Upon information and belief, Defendants had actual and constructive knowledge of the '218 patent prior to filing NDA No. 20-6968 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 Defendants)

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

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

46. Plaintiffs are further entitled to a declaration that, if Defendants, prior to patent expiry, commercially manufacture, use, offer for sale, or sell InnoPharma's Generic Product within the United States, import InnoPharma'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).

47. 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 Defendants infringed and are infringing each of the Patents-in-Suit;

B. A declaration that if Defendants, prior to patent expiry, commercially manufacture, use, offer for sale, or sell InnoPharma's Generic Product within the United States, import InnoPharma'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) that the effective date of any approval of Defendants' NDA No. 20-6968 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 any of InnoPharma'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 generic version of Cadence's OFIRMEV® brand product, or any other product that infringes or induce or contribute 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 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

/s/ Thomas C. Grimm

Thomas C. Grimm (#1098)
Jeremy A. Tigan (#5239)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
tgrimm@mnat.com
jtigan@mnat.com

Attorneys for Cadence Pharmaceuticals, Inc., SCR Pharmatop, and Mallinckrodt IP

OF COUNSEL:

Stephen P. Swinton
Darryl H. Steensma
LATHAM & WATKINS LLP
12670 High Bluff Drive
San Diego, CA 92130
(858) 523-5400

Kenneth G. Schuler
Marc N. Zubick
Emily C. Melvin
LATHAM & WATKINS LLP
330 North Wabash Avenue
Suite 2800
Chicago, IL 60611
(312) 876-7700

Parker M. Tresemer
LATHAM & WATKINS LLP
355 South Grand Avenue
Los Angeles, CA 90071
(213) 485-1234

Attorneys for Cadence Pharmaceuticals, Inc. and Mallinckrodt IP

Charles A. Weiss
HOLLAND & KNIGHT LLP
31 West 52nd Street
New York, NY 10019
(212) 513-3200

Attorney for SCR Pharmatop

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