IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CADENCE PHARMACEUTICALS, INC., SCR PHARMATOP, and MALLINCKRODT IP,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
AGILA SPECIALTIES PRIVATE LIMITED, INC. and AGILA SPECIALTIES INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Cadence Pharmaceuticals, Inc., SCR Pharmatop, and Mallinckrodt IP (collectively, "Plaintiffs") for their Complaint against defendants Agila Specialties Private Limited, Inc. and Agila Specialties 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 a 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,

Mulhuddart, 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 Agila Specialties Private Limited, Inc. ("Agila") is a Private Limited Liability Corporation having a principle place of business at Strides House, Bilekahalli, Bannerghatta Road, Bangalore, Karnataka, India, 560076. Upon information and belief, Agila is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, either on its own or through its affiliates, and Agila regularly conducts business in Delaware.

5. Upon information and belief, Defendant Agila Specialties Inc. ("Agila Specialties") is a New Jersey Corporation, having a principal place of business at 201 South Main Street, Suite #3, Lambertville, New Jersey 08530. Upon information and belief, Agila Specialties is the authorized United States agent for Agila. Upon information and belief, Agila Specialties is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, either on its own or through its affiliates, and Agila Specialties regularly conducts business in Delaware.

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 Agila because, *inter alia*, Agila has admitted to filing with the United States Food and Drug Administration (the "FDA") New Drug

Application ("NDA") No. 206-610 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. Based upon that admission, Agila has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of a tortious act of patent infringement as further detailed herein that has led to foreseeable harm and injury to Cadence, a Delaware corporation. This Court has personal jurisdiction over Agila 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 Agila because, *inter alia*, Agila 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, Agila regularly and continuously transacts business within the state of Delaware, either on its own or through its affiliates, including selling such pharmaceutical products as adenosine, ampicillin sodium, dexamethasone sodium phosphate, doxycycline hyclate, etomidate, famotidine, flumazenil, haloperidol lactate, lidocaine hydrochloride, nafcillin sodium, rifampin, vancomycin hydrochloride, and zoledronic acid. Upon information and belief, Agila has agreements with pharmaceutical retailers, wholesalers, or distributors providing for the distribution of its products in the State of Delaware.

11. Upon information and belief, Agila 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, Agila 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: *Cubist Pharm., Inc. v. Strides, Inc., et al.*, C.A. No. 13-1679-GMS (D. Del.).

13. Upon information and belief, Agila's systematic and continuous business contacts within Delaware render it at home in Delaware.

14. Upon information and belief, this Court has personal jurisdiction over Agila for the reasons stated herein, including, *inter alia*, Agila's activities in the forum, activities directed at the forum, significant contacts with the forum, and consent, all of which render Agila at home in the forum.

15. This Court also has personal jurisdiction over Agila under FEDERAL RULE OF CIVIL PROCEDURE 4(k)(2).

16. Upon information and belief, this Court has personal jurisdiction over Agila Specialties because, *inter alia*, Agila Specialties has committed, or aided, abetted, actively induced, contributed to, or participated together with Agila in the commission of a tortious act of patent infringement as further detailed herein through Agila's filing with the FDA of NDA No. 206-610 – for which Agila Specialties is designated as agent – 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 Agila Specialties for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

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

18. Upon information and belief, Agila Specialties regularly and continuously transacts business within the State of Delaware, either on its own or through its affiliates, including selling such pharmaceutical products as adenosine, ampicillin sodium, dexamethasone sodium phosphate, doxycycline hyclate, etomidate, famotidine, flumazenil, haloperidol lactate, lidocaine hydrochloride, nafcillin sodium, rifampin, vancomycin hydrochloride, and zoledronic acid. Upon information and belief, Agila Specialties 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.

19. In addition, Agila Specialties 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: *Cubist Pharm., Inc. v. Strides, Inc., et al.*, C.A. No. 13-1679-GMS (D. Del.); *Cephalon, Inc. v. Agila Specialties Inc., et al.*, C.A. No. 13-02080 (GMS) (D. Del.).

20. Upon information and belief, Agila Specialties' systematic and continuous business contacts within Delaware render it at home in Delaware.

21. Upon information and belief, this Court has personal jurisdiction over Agila Specialties for the reasons stated herein, including, *inter alia*, Agila Specialties' activities in the forum, activities directed at the forum, significant contacts with the forum, and consent, all of which render Agila Specialties at home in the forum.

22. 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 Pharm., Inc. et al. v. Exela Pharma Scis., LLC et al.*, C.A. No. 11-00733-LPS (D. Del.), including the Memorandum and Opinion dated November 14, 2013, the action

captioned *Cadence Pharm., Inc. et al. v. Wockhardt Ltd. et al.*, C.A. No. 1:14-cv-00094-LPS (D. Del.), including the Consent Judgment dated April 3, 2014, and the pending action captioned *Cadence Pharm., Inc. et al. v. InnoPharma Licensing LLC et al.*, C.A. No. 1:14-cv-01225-LPS (D. Del.).

THE PATENTS-IN-SUIT

23. 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.

24. 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.

25. 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.

26. 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.

27. 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®

28. Cadence holds approved NDA No. 022450 for OFIRMEV®, the first and only intravenous 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.

29. 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.

30. 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

31. Upon information and belief, Agila submitted NDA No. 206-610 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, offer for sale, and/or importation of acetaminophen for injection (“Agila’s Generic Product”), prior to the expiration of the Patents-in-Suit.

32. By a letter received by Plaintiffs on November 13, 2014 (the “Agila Letter”), Agila stated that it had submitted NDA No. 206-610 seeking approval to engage in the

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

33. The Agila Letter also states that NDA No. 206-610 contains a "Paragraph IV" certification that alleges the '222 patent and the '218 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale, offer for sale, or importation of Agila's Generic Product.

34. Upon information and belief, Agila has represented to the FDA that the components of Agila's Generic Product will have the same active ingredient as OFIRMEV®, will have the same route of administration as OFIRMEV®, and is bioequivalent to OFIRMEV®.

35. Agila's submission of NDA No. 206-610 to the FDA, including its section 355(b)(2)(A)(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 Agila'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), (c), and/or (g).

36. Defendants were aware of the Patents-in-Suit prior to filing NDA No. 206-610, and their actions render this an exceptional case under 35 U.S.C. § 285.

37. On information and belief, Agila and Agila Specialties collaborated and acted in concert in the decision to file and also in the filing of NDA No. 206-610.

38. 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)

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

40. Defendant Agila’s submission of NDA No. 206-610, including their inclusion of section 355(b)(2)(A)(iv) allegations, constitutes infringement of the ’222 patent pursuant to 35 U.S.C. § 271(e)(2) by Defendants.

41. On information and belief, upon FDA approval of NDA No. 206-610, Defendants will infringe the ’222 patent by making, using, offering to sell, or selling Agila’s Generic Product in the United States and/or importing Agila’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), (c), and/or (g).

42. Upon information and belief, Defendants had actual and constructive knowledge of the ’222 patent prior to filing NDA No. 206-610 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)

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 Agila’s Generic Product within the United States, import Agila’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), (c), and/or (g).

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.

COUNT III
(Infringement of the '218 Patent by Defendants)

47. Plaintiffs incorporate each of the preceding paragraphs 1 to 46 as if fully set forth herein.

48. Defendant Agila's submission of NDA No. 206-610, including their inclusion of section 355 (b)(2)(A)(iv) allegations, constitutes infringement of the '218 patent pursuant to 35 U.S.C. § 271(e)(2) by Defendants.

49. Upon FDA approval of NDA No. 206-610, Defendants will infringe the '218 patent by making, using, offering to sell, or selling Agila's Generic Product in the United States and/or importing Agila'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), (c), and/or (g).

50. Upon information and belief, Defendants had actual and constructive knowledge of the '218 patent prior to filing NDA No. 206-610 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)

51. Plaintiffs incorporate each of the preceding paragraphs 1 to 50 as if fully set forth herein.

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

53. Plaintiffs are further entitled to a declaration that, if Defendants, prior to patent expiry, commercially manufacture, use, offer for sale, or sell Agila's Generic Product within the United States, import Agila'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), (c), and/or (g).

54. 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 Agila's Generic Product within the United States, import Agila's Generic Product into the United States, or induce or contribute to such conduct, Defendants would infringe the Patents-in-Suit;

C. An order issued pursuant to 35 U.S.C. § 271(e)(4) that the effective date of any approval of NDA No. 206-610 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 Agila'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 to Plaintiffs of their 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

/s/ Thomas C. Grimm

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