UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

CADENCE PHARMACEUTICALS, INC.; and SCR PHARMATOP, Plaintiffs, v. EXELA PHARMA SCIENCES, LLC; EXELA PHARMSCI, INC.; and EXELA HOLDINGS, INC.; Defendants.	C.A. No. _____

COMPLAINT

Plaintiffs Cadence Pharmaceuticals, Inc. and SCR Pharmatop (collectively, "Plaintiffs") for their Complaint against defendants Exela Pharma Sciences, LLC; Exela PharmSci, Inc.; and Exela Holdings, 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 12481 High Bluff Drive, Suite 200, San Diego, California, 92130.

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.

3. Upon information and belief, defendant Exela Pharma Sciences, LLC ("Exela Pharma Sciences") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1325 William White Place, Lenoir, North Carolina, 28645. Upon

information and belief, Exela Pharma Sciences is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, including in this judicial district.

4. Upon information and belief, defendant Exela PharmSci, Inc. ("Exela PharmSci") is a corporation organized and existing under the laws of the State of Virginia, with its headquarters at 19978 Palmer Classic Parkway, Ashburn, Virginia, 20147. Upon information and belief, Exela PharmSci is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, including in this judicial district. Upon information and belief, Exela Pharma Sciences is a wholly owned subsidiary of Exela PharmSci.

5. Upon information and belief, defendant Exela Holdings, Inc. ("Exela Holdings") is an entity organized under the laws of the State of Delaware, with its headquarters at 19978 Palmer Classic Parkway, Ashburn, Virginia, 20147. Upon information and belief, Exela Holdings is in the business of manufacturing, distributing, and selling pharmaceutical products throughout the United States, including in this judicial district. Upon information and belief, Exela Holdings is the parent company of defendants Exela Pharma Sciences and Exela PharmSci.

NATURE OF THE ACTION

6. 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 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 Exela Pharma Sciences by virtue of, *inter alia*, Exela Pharma Sciences' continuous presence and principal place of business in the State of North Carolina.

9. This Court has personal jurisdiction over Exela PharmSci by virtue of, *inter alia*, (1) its presence in North Carolina through its subsidiary Exela Pharma Sciences; and (2) its systematic and continuous contacts with North Carolina, including through its subsidiary Exela Pharma Sciences.

10. This Court has personal jurisdiction over Exela Holdings by virtue of, *inter alia*, (1) its presence in North Carolina through its subsidiary Exela Pharma Sciences; and (2) its systematic and continuous contacts with North Carolina, including through its subsidiary Exela Pharma Sciences.

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

THE PATENTS-IN-SUIT

12. 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.

13. 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**.

14. 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.

15. 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®

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. 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.

17. 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

18. Upon information and belief, Exela Pharma Sciences submitted, Abbreviated New Drug Application ("ANDA") No. 20-3092 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 ("Exela's Generic Product"), as a generic version of the OFIRMEV® product, prior to the expiration of the Patents-in-Suit.

19. By a letter dated July 12, 2011 (the "Exela Letter"), Exela Pharma Sciences stated that it had submitted ANDA No. 20-3092 seeking approval to engage in the commercial manufacture,

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

20. The Exela Letter also stated that ANDA No. 20-3092 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that alleges the '222 patent and '218 patent are invalid and that Exela's Generic Product will not infringe any of the claims of the Patents-in-Suit.

21. Cadence received notice of ANDA No. 30-3092 and the section 355(j)(2)(A)(vii)(IV) allegations on or about July 13, 2011. However, neither Pharmatop nor Pharmatop's representative have received notice from Exela Pharma Sciences, as required under 21 USC § 355(j)(2)(B)(iii) and 21 CFR 314.52(a).

22. By filing ANDA No. 20-3092, Exela Pharma Sciences necessarily represented to the FDA that the components of Exela'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®.

23. Exela Pharma Sciences' submission of ANDA No. 20-3092 to the FDA, including the 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 Defendants commercially manufacture, import, use, offer for sale, or sell Exela'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).

24. Exela Holdings and Exela PharmSci are jointly and severally liable for infringement of the Patents-in Suit. Upon information and belief, Exela Holdings and Exela PharmSci participated in, contributed to, aided, abetted and/or induced Exela Pharma Sciences' submission of ANDA No. 20-3092 and its section 355(j)(2)(A)(vii)(IV) allegations to the FDA.

25. The Defendants were aware of the Patents-in-Suit prior to filing ANDA No. 20-3092,

and their actions render this an exceptional case under 35 U.S.C. § 285.

26. 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)

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

28. Exela Pharma Sciences' submission of ANDA No. 20-3092, 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.

29. Upon FDA approval of ANDA No. 20-3092, Defendants will infringe the '222 patent by making, using, offering to sell, or selling Exela's Generic Product in the United States and/or importing Exela'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).

30. Upon information and belief, Defendants had actual and constructive knowledge of the '222 patent prior to filing ANDA No. 20-3092 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)

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

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

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

States, import Exela'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).

34. 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)

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

36. Exela Pharma Sciences' submission of ANDA No. 20-3092, including the section 355(j)(2)(A)(vii)(IV) allegation, constitutes infringement of the '218 patent pursuant to 35 U.S.C. § 271(e)(2) by Defendants.

37. Upon FDA approval of ANDA No. 20-3092, Defendants will infringe the '218 patent by making, using, offering to sell, or selling Exela's Generic Product in the United States and/or importing Exela'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).

38. Upon information and belief, Defendants had actual and constructive knowledge of the '218 patent prior to filing ANDA No. 20-3092 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)

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

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

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

States, import Exela'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).

42. 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 the Defendants have 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 Defendants' ANDA No. 20-3092 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 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 Exela'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 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 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.

s/KATHLEEN K. LUCCHESI
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