

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION - LEXINGTON**

UCB, INC., UCB BIOPHARMA SRL, AND
RESEARCH CORPORATION
TECHNOLOGIES, INC.,

Plaintiffs,

v.

CATALENT PHARMA SOLUTIONS, INC.,
CATALENT PHARMA SOLUTIONS, LLC,
AND CATALENT INC.

Defendant.

Civil Action No. 5:21-cv-00038-GFVT

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs UCB, Inc., UCB BioPharma SRL, and Research Corporation Technologies, Inc. (collectively, “UCB” or “Plaintiffs”), by their undersigned attorneys, bring this action against Defendants Catalent Pharma Solutions, Inc., Catalent Pharma Solutions, LLC, and Catalent, Inc. (collectively, “Catalent” or “Defendants”), and hereby allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, arises from Defendants’ manufacture, use, offer for sale, sale, and/or importation of the pharmaceutical ingredient, lacosamide.

2. Lacosamide, an anticonvulsant, is the active pharmaceutical ingredient in Plaintiff UCB’s drug product, VIMPAT®. VIMPAT® tablets, injections, and oral solutions are indicated as treatment of partial-onset seizures in patients 4 years of age and older and as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older.

3. The compound lacosamide is claimed by United States Reissued Patent No. RE38,551 (the “’551 Patent”) in at least claims 9, 10, and 13, of the ’551 Patent.

4. The validity of claims 9, 10, and 13, of the ’551 Patent have been upheld by the Patent Trials and Appeals Board, the United States Patent and Trademark Office, the United States District Court for the District of Delaware, and the United States Court of Appeals for the Federal Circuit.

5. Despite the unambiguous judgments of the Patent Trials and Appeals Board, the United States Patent and Trademark Office, the United States District Court for the District of Delaware, and the United States Court of Appeals for the Federal Circuit, Defendants have infringed, and continue to infringe, the ’551 Patent claims by importation of lacosamide into, and through its manufacturing, use, sale, and/or offer for sale of lacosamide in, the United States.

6. Plaintiffs bring this action, and the accompanying motion for immediate interim injunctive relief, in order that this Court enjoin Defendants’ infringement of the ’551 Patent, order the seizure of all lacosamide, including products comprising lacosamide, in Defendants’ custody or control, and otherwise relieve and redress the injury to Plaintiffs caused by Defendants’ infringement.

THE PARTIES

7. Plaintiff UCB, Inc., is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 1950 Lake Park Drive, Smyrna, Georgia 30080.

8. Plaintiff UCB BioPharma SRL is a corporation organized and existing under the laws of Belgium, having an office and place of business at Allée de la Recherche 60, B-1070 Brussels, Belgium.

9. Plaintiff Research Corporation Technologies, Inc. (“RCT”) is a nonprofit corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 6440 N. Swan Road, Suite 200, Tucson, Arizona 85718.

10. On information and belief, Defendant Catalent Pharma Solutions, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 14 Schoolhouse Road, Somerset, New Jersey 08873.

11. On information and belief, Defendant Catalent Pharma Solutions, Inc., is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 14 Schoolhouse Road, Somerset, New Jersey 08873.

12. On information and belief, Defendant Catalent, Inc., is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 14 Schoolhouse Road, Somerset, New Jersey 08873.

13. On information and belief, Catalent Pharma Solutions, Inc., and Catalent Pharma Solutions, LLC are each wholly owned subsidiaries of Catalent, Inc.

JURISDICTION AND VENUE

14. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271.

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

16. Catalent’s contacts with the Commonwealth of Kentucky are such that Catalent is “at home” in the Commonwealth, including in this District.

17. On information and belief, Catalent Pharma Solutions, LLC is registered to do business in the Commonwealth of Kentucky under Organization Number 0573548 and has a

registered agent in the Commonwealth of Kentucky located at Corporation Service Company, 421 West Main Street, Frankfort, Kentucky 40601.

18. Defendants have a regular and established place of business in this District. On information and belief, Catalent Pharma Solutions, LLC, Catalent Pharma Solutions, Inc., and/or Catalent, Inc., own and operate a 180,000 square foot manufacturing facility located at 1100 Enterprise Drive, Winchester, KY 40391. Catalent describes the Winchester facility as “the flagship US manufacturing location for large scale oral dose forms, with integrated analytical and development services. With 28 years of expertise in product development, technology transfers and commercial manufacturing, and roots in industry-leading Glatt technology.”¹

19. This Court has personal jurisdiction over Defendants because, on information and belief, Defendants, individually and together, *inter alia*, have continuous and systematic contacts with the Commonwealth of Kentucky; regularly conduct business in the Commonwealth of Kentucky, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos; and have purposefully availed themselves of the privilege of doing business in the Commonwealth of Kentucky.

20. On information and belief, Defendants, individually and together, are in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which the Defendants manufacture, distribute, market, and/or sell throughout the United States and in this District.

¹ See <https://www.catalent.com/our-locations/north-america/winchester-usa/> (last accessed February 24, 2021).

21. On information and belief, Defendants commercialize over 180 drug products annually, manufacture over 70 billion drug doses annually, and have partnerships with pharmaceutical and biopharmaceutical companies across the world, including companies within the United States and the Commonwealth of Kentucky.²

22. Defendants have committed acts of infringement in this District. On information and belief, Defendants, individually and together, have made, used, offered to sell, sold, and/or imported lacosamide, and/or drug products comprising lacosamide, in the Commonwealth of Kentucky, either directly or through one or more wholly owned subsidiaries, agents, and/or alter egos.

23. On information and belief, Defendants, individually and together, know and intend that their lacosamide drug products will be distributed and sold in the United States, including in the Commonwealth of Kentucky, including in this District, causing injury to UCB. On further information and belief, Defendants, individually and together, intend to take advantage of their established channels of distribution within the Commonwealth of Kentucky and beyond for the sale of its lacosamide drug product.

24. Venue is proper in this district for Defendants pursuant to 28 U.S.C. §§ 1391 and 1400(b).

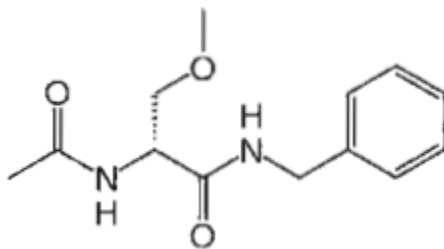
THE PATENT-IN-SUIT

25. The '551 Patent, entitled "Anticonvulsant Enantiomeric Amino Acid Derivatives," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO") on July 6, 2004. A true and correct copy of the '551 Patent is attached hereto as **Exhibit A**.

² See <https://www.catalent.com/about-us/overview/> (last accessed February 24, 2021).

26. The '551 Patent is assigned to Plaintiff RCT. RCT granted an exclusive patent license to Harris FRC Corporation ("Harris FRC")³ to manufacture, use, sell, offer to sell, and import lacosamide. Harris FRC exclusively sublicensed the rights to the '551 Patent to Schwarz Pharma AG ("Schwarz"). UCB and its affiliates acquired Schwarz and all of its rights in the '551 Patent. Assignment and change of name documents establishing ownership were recorded with the USPTO.

27. The '551 Patent claims, *inter alia*, the chemical compound lacosamide, therapeutic compositions comprising lacosamide, and methods of treating central nervous system disorders comprising administering lacosamide. Lacosamide is known chemically as (R)-2-acetamido-N-benzyl-3-methoxypropionamide or (R)-N-benzyl-2-acetamido-3-methoxypropionamide. The chemical structure of lacosamide is:



28. The term of the '551 Patent expires on March 17, 2022.

PLAINTIFFS' LACOSAMIDE PRODUCT, VIMPAT®

29. UCB, Inc., holds approved New Drug Application ("NDA") No. 022253, for VIMPAT® tablets (50 mg, 100 mg, 150 mg, and 200 mg dosage strengths), which contain lacosamide as the active ingredient. The FDA approved NDA No. 022253, on October 28, 2008.

³ Harris FRC Acquisition, LP has since purchased Harris FRC's intellectual property and other rights related to lacosamide.

UCB lists the '551 Patent in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 022253.

30. UCB, Inc., holds approved NDA No. 022254 for VIMPAT[®] intravenous solution (200 mg/20 mL dosage strength), which contains lacosamide as the active ingredient. The FDA approved NDA No. 022254 on October 28, 2008. UCB lists the '551 Patent in the Orange Book for NDA No. 022254.

31. UCB, Inc., holds approved NDA No. 022255 for VIMPAT[®] oral solution (10 mg/mL dosage strength), which contains lacosamide as the active ingredient. The FDA approved NDA No. 022255 on April 20, 2010. UCB lists the '551 Patent in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 022255.

32. VIMPAT[®] tablets, injections, and oral solutions are indicated as treatment of partial-onset seizures in patients 4 years of age and older and as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older.

33. Plaintiff UCB sells, and offers for sale, lacosamide, through its various VIMPAT[®] formulations, throughout the United States, including in this District.

PRIOR ADJUDICATION OF THE '551 PATENT

34. On August 12, 2016, the U.S. District Court for the District of Delaware issued an Order reflecting that the generic drug manufacturer defendants in that action had stipulated that their drug products proposed for approval by the FDA and comprising the active ingredient lacosamide infringe claims 9, 10, and 13, of the '551 Patent, and that those defendants had failed to prove that any of claims 9, 10, and 13, of the '551 Patent are invalid for any reason asserted. *See UCB, Inc., et al., v. Accord Healthcare, Inc., et al.*, C.A. No. 13-1206-LPS, D.I. 313, 314 (D. Del. Aug. 12, 2016) (unsealed Aug. 15, 2016).

35. In view of its Order, on September 2, 2016, the Delaware District Court entered a Final Judgment in favor of Plaintiffs and ordered that the defendants to the action, including MSN Laboratories Pvt. Ltd., along with their “officers, agents, servants...and those persons in active concert or participation with them who receive actual notice of the Final Judgment” are enjoined from infringing activity related to lacosamide until expiration of the ’551 Patent (the “Delaware Injunction”). *See UCB, Inc., et al., v. Accord Healthcare, Inc., et al.*, C.A. No. 13-1206-LPS, D.I. 323 (D. Del. Sept. 2, 2016).

36. On May 23, 2018, the United States Court of Appeals for the Federal Circuit affirmed the 2016 judgment of the District of Delaware that claims 9, 10, and 13, of the ’551 Patent, which claim the chemical compound lacosamide, therapeutic compositions comprising lacosamide, and methods of treatment using such therapeutic compositions, are not invalid. *See UCB, Inc., et al., v. Accord Healthcare, Inc., et al.*, C.A. No. 13-1206-LPS, D.I. 343 (D. Del. May 23, 2018).

CATALENT’S INFRINGEMENT OF THE ’551 PATENT

37. On information and belief, on or about April 2, 2019, Catalent caused MSN Pharmachem Private Limited, to import approximately 1.7 grams of lacosamide into the United States by way of an international airport located in or around Louisville, Kentucky.

38. On information and belief, on or about May 16, 2019, Catalent caused MSN Pharmachem Private Limited, to import two separate shipments of approximately 48 kilograms (96 kilograms total) of lacosamide into the United States by way of an international airport located in or around Louisville, Kentucky.

39. On information and belief, on or about July 6, 2019, Catalent caused MSN Pharmachem Private Limited, to import approximately 200 kilograms of lacosamide into the United States by way of an international airport located in or around Louisville, Kentucky.

40. On information and belief, on or about December 10, 2019, Catalent caused MSN Pharmachem Private Limited, to import approximately 50 kilograms of lacosamide into the United States by way of an international airport located in or around Louisville, Kentucky.

41. On information and belief, on or about May 22, 2020, Catalent caused MSN Pharmachem Private Limited, to import approximately 90 kilograms of lacosamide into the United States by way of an international airport located in or around New York, NY.

42. On information and belief, on or about June 8, 2020, Catalent caused MSN Pharmachem Private Limited, to import approximately 90 kilograms of lacosamide into the United States by way of an international airport located in or around New York, NY.

43. On information and belief, on or about September 10, 2020, Catalent caused MSN Pharmachem Private Limited, to import approximately 43 kilograms of lacosamide into the United States by way of an international airport located in or around Cincinnati, OH.

44. On information and belief, Catalent has caused the importation of over 550 kilograms of lacosamide into the United States.

45. On information and belief, Catalent has used, manufactured, sold, and/or offered for sale lacosamide, and/or drug products comprising lacosamide in the United States.

46. On information and belief, Catalent's actions related to lacosamide have been and remain undertaken for commercial purposes.

47. Catalent's actions related to lacosamide infringe the claims of the '551 Patent, including at least claims 9, 10, and 13.

48. On information and belief, MSN Pharmachem Private Limited is an agent or servant of MSN Laboratories Pvt. Ltd. at least by way of its existence as a subsidiary of MSN Laboratories Pvt. Ltd.

49. MSN Laboratories Pvt. Ltd. was a party to the civil action *UCB, Inc., et al., v. Accord Healthcare, Inc., et al.*, C.A. No. 13-1206-LPS, and, along with “officers, agents, servants...and those persons in active concert or participation with them who receive actual notice of the Final Judgment,” is subject to the Delaware Injunction. *See* D.I. 323 (D. Del. Sept. 2, 2016).

50. On information and belief, as an agent or servant of MSN Laboratories Pvt. Ltd., MSN Pharmachem Private Limited is subject to the Delaware Injunction.

51. On information and belief, Defendant Catalent, at least through its importation of lacosamide, caused or otherwise abetted MSN Pharmachem Private Limited to violate the Delaware Injunction.

52. On information and belief, Catalent has at all relevant times had actual notice of the District of Delaware’s 2016 Final Judgment and the Delaware Injunction, by its knowing participation and/or acts in concert with MSN Pharmachem Private Limited in importing lacosamide into the United States, itself has induced the violated that United States Court Order.

COUNT I
INFRINGEMENT OF THE ’551 PATENT BY CATALENT

53. Plaintiffs restate, reallege, and incorporate each of the preceding paragraphs as if fully set forth herein.

54. On information and belief, Catalent has made, used, offered for sale, and/or sold lacosamide within the United States.

55. Catalent has imported lacosamide into the United States.

56. There is a justiciable controversy between the parties hereto as to the infringement of the ’551 Patent.

57. Catalent has infringed one or more claims of the '551 Patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling and/or importing subject matter claimed by the '551 Patent.

58. Catalent has induced infringement of one or more claims of the '551 Patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing subject matter claimed by the '551 Patent. On information and belief, Catalent intentionally encouraged acts of direct infringement with knowledge of the '551 Patent and knowledge that its acts are encouraging infringement by others, including MSN Pharmachem Private Limited, to, for example, import lacosamide into the United States for Catalent's benefit.

59. Catalent has contributorily infringed one or more claims of the '551 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing subject matter claimed by the '551 Patent. On information and belief, Catalent has had and continues to have knowledge that others', including their customers', commercial partners', and/or affiliates' actions are especially adapted to infringe one or more claims of the '551 Patent and that there is no substantial non-infringing purpose for those actions.

60. Catalent has infringed of one or more claims of the '551 Patent under 35 U.S.C. § 271(f) by supplying or causing to be supplied in or from the United States the subject matter claimed by the '551 Patent. On information and belief, Catalent has actively induced the preparation of drug product, inside and/or outside the United States, comprising the active ingredient lacosamide in a manner that infringes one or more claims of the '551 Patent.

61. Plaintiffs will be substantially and irreparably damaged and harmed if Catalent's infringement of the '551 Patent is not enjoined.

62. Catalent's infringement is willful, and Plaintiffs are entitled to treble damages under 35 U.S.C. § 284.

63. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Defendants and respectfully requests the following relief:

(A) A judgment that Defendants have infringed the '551 Patent by making, using, offering to sell, selling, or importing lacosamide into the United States, or inducing or contributing to such conduct, pursuant to 35 U.S.C. § 271;

(B) Entry of preliminary and permanent injunctions enjoining Defendants, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in active concert or participation with it or on its behalf, from commercially manufacturing, using, offering for sale, or selling lacosamide, or any products comprising lacosamide, within the United States, or importing lacosamide, or any products comprising lacosamide, into the United States, until the expiration of the '551 Patent, including any extensions, adjustments, and exclusivities applicable to the '551 Patent, and from otherwise infringing the claims of the '551 Patent;

(C) An award of damages or other monetary relief, together with interest, for Defendants' manufacture, use, offer for sale, sale, and/or importation of lacosamide, or any product that infringes the '551 Patent including products comprising lacosamide, or induces or contributes to such conduct, prior to the expiration of the '551 Patent including any extensions, adjustments, and exclusivities applicable to the '551 Patent;

(D) A judgment and order finding that Defendants' infringement is willful pursuant to 35 U.S.C. § 284, and awarding to UCB treble damages;

(E) A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to UCB its reasonable attorneys' fees;

(F) One or more sanctions against Defendants for inducing, or otherwise acting in concert, in the violation of existing Orders of the United States courts, at least including the Delaware Injunction, as the Court deems appropriate;

(G) Awarding UCB its costs and expenses in this action; and

(H) Granting any and all other relief as the Court deems just and proper.

Dated: February 24, 2021

DUNCAN GALLOWAY EGAN GREENWALD, PLLC

OF COUNSEL:

James Trainor
Robert Counihan
FENWICK & WEST LLP
902 Broadway, Suite 14
New York, NY 10010-6035
(212) 430-2600

*Attorneys for Plaintiffs UCB, Inc., UCB
BioPharma SRL, and Research Corporation
Technologies, Inc.*

By: /s/ Bart Greenwald
Bart Greenwald
Kevin Duncan
DUNCAN GALLOWAY EGAN GREENWALD, PLLC
9625 Ormsby Station Road
Louisville, KY 40223
(502) 614-6974

*Attorneys for Plaintiffs UCB, Inc., UCB
BioPharma SRL, and Research Corporation
Technologies, Inc.*