

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

METACEL PHARMACEUTICALS LLC,

Plaintiff,

v.

**RUBICON RESEARCH PRIVATE
LIMITED,**

Defendant.

Civil Action No. _____

Document Filed Electronically

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Metacel Pharmaceuticals LLC (“Metacel”), by and through its undersigned counsel, hereby files this Complaint for Patent Infringement against Defendant Rubicon Research Private Limited (“Rubicon”), respectfully showing this Court as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 10,610,502 (the “’502 Patent”) owned by Metacel and arising under the patent laws of the United States, Title 35, United States Code, Sections 100 *et seq.*

2. This action relates to a supplemental Abbreviated New Drug Application (Number 214445/S-001) that supplements Abbreviated New Drug Application (“ANDA”) No. 214445 filed by Rubicon with the United States Food and Drug Administration (“FDA”) for approval to market a generic version of Metacel’s Ozobax® drug product prior to the expiration of ’502 Patent.

PARTIES, JURISDICTION AND VENUE

3. Metacel is a domestic limited liability company organized and existing under the laws of the State of Georgia, having a principal place of business at 1272 Virgil Langford Road, Suite 201C, Watkinsville, Georgia, 30677.

4. On information and belief, Rubicon is a corporation organized and existing under the laws of India, having a principal place of business at 221 Annex Building, Goregaon Mulund Link Road Bhandup (West) Mumbai, 400 078 India.

5. Rubicon also maintains a business development and regulatory office in the United States at 666 Plainsboro Road, Suite 605, Plainsboro, New Jersey 08536.

6. Rubicon has authorized Timothy H. Kratz, Kratz & Barry LLP, 1050 Crown Pointe Parkway, Suite 500, Atlanta, Georgia 30338 to accept service and process on its behalf.

7. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a) (patent infringement) and 28 U.S.C. §§ 2201 and 2202 (declaratory judgment).

8. Rubicon's development and regulatory office is located in New Jersey.

9. On information and belief, Rubicon is in the business of, among other things, formulating, developing, manufacturing, packaging, marketing, and selling generic versions of brand-name pharmaceutical products for the United States market, including in New Jersey.

10. On information and belief, Rubicon, directly or through its affiliates and agents, formulates, manufactures, packages, markets, and/or sells pharmaceutical products throughout the United States and in New Jersey.

11. Additionally, upon information and belief, Rubicon prepared supplemental Abbreviated New Drug Application (Number 214445/S-001) at their New Jersey office, thus committing the act of patent infringement within this district. *See* 35 U.S.C. § 271(e)(2).

12. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery, this Court has personal jurisdiction over Rubicon because, Rubicon has purposely availed itself of the rights and benefits of the laws of New Jersey by engaging in systematic and continuous contacts with the state such that it should reasonably anticipate being haled into court here.

13. In the alternative, this Court has personal jurisdiction over Rubicon pursuant to Federal Rule of Civil Procedure 4(k)(20)(A).

14. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b) because Rubicon has committed acts of infringement and has a regular and established place of business in this district.

THE PATENT-IN-SUIT

15. On April 7, 2020, the U.S. Patent and Trademark Office duly and legally issued the '502 Patent, titled "Oral Baclofen Solutions."

16. Metacel is the owner of the '502 Patent.

17. A true and correct copy of the '502 Patent is attached as **Exhibit A**.

18. The claims of the '502 Patent carry a presumption of validity under 35 U.S.C. § 282(a) and are enforceable.

19. The '502 Patent does not expire until August 30, 2039, which date may be extended if Metacel is or becomes entitled to any extensions and/or additional periods of exclusivity.

METACEL'S BRAND-NAME DRUG

20. Metacel is the holder of approved New Drug Application (NDA) No. 208193 for its baclofen oral solution 5mg/5mL, which Metacel markets in the United States under the name Ozobax®.

21. As noticed in Rubicon’s Paragraph IV letter, pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(1), and FDA regulations, the ’502 Patent has been listed in the FDA publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) with respect to Metacel’s Ozobax® brand drug product.

22. The composition and formulation for Metacel’s Ozobax® brand drug product is covered by certain claims of the ’502 Patent.

RUBICON’S GENERIC DRUG PRODUCT

23. On September 15, 2021, Rubicon sent Metacel a letter (the “September 15th Paragraph IV Notification”) notifying Metacel that it had submitted ANDA No. 214445 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to commercially manufacture, use, offer for sale, and sell a baclofen oral solution 5mg/5mL (“Rubicon’s ANDA Product”) before the expiration of the ’502 Patent.

24. In its September 15th Paragraph IV Notification, Rubicon notified Metacel that its ANDA contained a “paragraph IV certification,” asserting that certain claims of the ’502 Patent were invalid, unenforceable and/or would not be infringed by the commercial manufacture, use, and sale of Rubicon’s ANDA Product.

25. On October 29, 2021, Metacel initiated a patent infringement action against Rubicon in this Court in the case styled, *Metacel Pharmaceuticals LLC v. Rubicon Research Private Ltd.*, Case No. 2:21-cv-19463-EP-JRA. On July 7, 2023, this Court granted summary judgment in favor of Rubicon, finding that Rubicon’s ANDA Product did not infringe the ’502 Patent. On July 21, 2023, Metacel moved for reconsideration on this Court’s grant of summary judgment, which this Court denied by issuing its August 31, 2023 Order (“the August Order”). The August Order only addressed the “Fridge Limitation,” i.e., the storage condition limitation of the ’502 Patent. (Dkt. No. 158). The

Court's ruling is currently on appeal before the United States Court of Appeals for the Federal Circuit (the "Federal Circuit") in the case styled, *Metacel Pharmaceuticals LLC v. Rubicon Research Private Ltd.*, Case No. 2023-2386 (the "Appeal").

26. By letter dated January 6, 2025 (the "January 6th Paragraph IV Notification"), Rubicon notified Metacel that it had submitted a supplemental ANDA for Rubicon's ANDA Product ("Rubicon's supplemental ANDA Product").

27. The name of Rubicon's supplemental ANDA Product is the same as its original ANDA Product—"baclofen oral solution 5mg/5mL."

28. The FDA assigned application number 214445/S-001 to Rubicon's supplemental ANDA (the "supplemental ANDA").

29. The formulation referenced in Rubicon's supplemental ANDA shares similarities to the formulation in its prior ANDA, including the active ingredient, but includes different excipients in different amounts with different underlying compositions.

30. While Rubicon's supplemental ANDA does not specify the purpose of these excipient modifications, upon information and belief, these changes may be intended to affect the storage conditions of the product, which on information and belief, depart from this Court's prior findings related to the '502 Patent by raising new issues of fact and law.

31. On information and belief, the altered excipients lead to infringement of the buffer limitation of the '502 Patent.

32. On information and belief, Rubicon conducts testing that satisfies the impurity limitation of the '502 Patent.

33. In its January 6th Paragraph IV Notification, Rubicon notified Metacel that its supplemental ANDA contained a “paragraph IV certification,” asserting that its supplemental ANDA does not infringe on the ’502 Patent for the reasons set forth in the August Order.

34. As stated above, the August Order is currently on appeal before the Federal Circuit in the Appeal and only relates to the storage limitation of the ’502 Patent.

35. Rubicon’s January 6th Paragraph IV Notification relies on an order that is the subject of a pending appeal.

36. Aside from citing the August Order, the January 6th Paragraph IV Notification does not provide any independent reasoning or factual bases to support Rubicon’s assertion that the ’502 Patent is invalid, unenforceable, and/or will not be infringed by Rubicon’s supplemental ANDA Product.

37. Even if the August Order were considered to provide a basis for non-infringement, its reasoning addresses only a portion of the ’502 Patent—specifically, the recommended storage conditions for the ANDA Product stated on the label.

38. On information and belief, at the time of the January 6th Paragraph IV Notification, Rubicon’s ANDA No. 214445/S-001 had been received by the FDA.

39. Notably, Rubicon’s supplemental ANDA does not include a label for Rubicon’s supplemental ANDA Product, which would display the information that downstream users such as physicians, pharmacists, and patients would consult when storing the supplemental ANDA product.

40. The FDA requires that an ANDA submission include a complete and accurate product label that demonstrates compliance with regulatory requirements. The absence of a label in Rubicon’s supplemental ANDA raises questions on the satisfaction of the applicable regulatory

requirements, and without that express information, on information and belief, Rubicon or downstream users would store the supplemental ANDA product as claimed in the '502 Patent.

41. And given the changes to the formulation of the supplemental ANDA, the product label would be different than the original ANDA label.

42. Moreover, without a proposed label, the supplemental ANDA does not indicate the conditions under which the public would be instructed to store Rubicon's supplemental ANDA product and references in the supplemental ANDA recommend storage conditions that fall within the scope of the '502 Patent claims.

43. On information and belief, Rubicon knows that ANDA No. 214445/S-001 did not include the label for the supplemental ANDA Product.

44. Upon information and belief, Rubicon has taken or will take active steps to intentionally encourage physicians, pharmacists, and/or patients to store Rubicon's supplemental ANDA Product in a manner that infringes the '502 Patent.

45. Upon information and belief, although the composition in the supplemental ANDA is different than the formulation in the ANDA, the formulation of Rubicon's supplemental ANDA Product infringes the '502 Patent for similar reasons alleged in the prior litigation, namely, that the supplemental ANDA infringes each and every limitation of claims 1 and/or 2 either literally or under the doctrine of equivalents.

46. Upon information and belief, Rubicon intends to engage in the commercial manufacture, use, and sale of Rubicon's supplemental ANDA Product promptly upon receiving FDA approval to do so.

47. Upon receiving FDA approval, Rubicon will, either directly or indirectly, promote the substitution of its generic baclofen oral solution for Metacel's Ozobax® brand baclofen oral

solution, which will cause at least a portion of the market for Ozobax® to convert to Rubicon's generic baclofen oral solution.

48. The commercial manufacture, use, offer for sale, sale, and/or importation of Rubicon's supplemental ANDA Product before the expiration of the '502 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '502 Patent, either literally or under the doctrine of equivalents.

49. This Complaint is being filed before the expiration of the forty-five days from the date Metacel received the January 6th Paragraph IV Notification.

COUNT I: INFRINGEMENT OF THE '502 PATENT

50. Metacel incorporates the foregoing paragraphs as if fully restated herein.

51. Rubicon has actual knowledge of the '502 Patent. Rubicon's knowledge and intent is demonstrated by, among other things, the listing of the '502 Patent in the Orange Book, the ongoing litigation between the parties concerning Rubicon's infringement of the '502 Patent, and Rubicon's Notice Letter and Rubicon's January 6th Paragraph IV Notification.

52. Rubicon's submission of ANDA No. 214445/S-001 to obtain approval for the commercial manufacture, use, offer for sale, sale, or importation of Rubicon's supplemental ANDA Product—prior to the expiration of the '502 Patent—constitutes an act of infringement of claims 1 and/or 2 under 35 U.S.C. § 271(e)(2)(A).

53. Upon FDA approval of Rubicon's ANDA No. 214445/S-001, Rubicon will further infringe the '502 Patent under 35 U.S.C. § 271(a), (b) and/or (c), by making, using, offering for sale, selling and/or importing Rubicon's supplemental ANDA Product in the United States.

54. For example, Rubicon's Supplemental ANDA Product is identical in key respects to Metacel's Ozobax®, including having the same active ingredient (baclofen), the same dosage strength (5mg/5mL), and the same dosage form (oral solution).

55. In addition, Rubicon will manufacture or direct the manufacture of the composition of claims 1 and/or 2 of the '502 Patent.

56. Therefore, the commercial manufacture, use, offer for sale, sale, or importation of Rubicon's supplemental ANDA Product will directly infringe claims 1 and/or 2 of the '502 Patent.

57. Upon information and belief, once Rubicon's supplemental ANDA Product is offered for sale or sold, Rubicon will indirectly infringe the '502 Patent by inducing and/or contributing to infringement by others, including manufacturers, distributors, healthcare professionals, pharmacists, and/or patients.

58. Upon information and belief, physicians, pharmacists, and/or patients will directly infringe claims 1 and/or 2 of the '502 Patent by storing the supplemental ANDA product in the same manner as Ozobax®, based upon references in the supplemental ANDA and in accordance with standard practice and established expectations for the product.

59. Rubicon knows and intends that its generic baclofen product will be used in a manner that infringes claims 1 and/or 2 of the '502 Patent.

60. Rubicon's supplemental ANDA Product has no substantial non-infringing use and its January 6th Paragraph IV Notification relies solely on an order that remains subject to a pending appeal.

61. If Rubicon's infringement of the '502 Patent is not enjoined, Metacel will suffer substantial irreparable harm for which there is no adequate remedy at law.

62. Under 35 U.S.C. § 271(e)(4), Metacel is entitled to full relief from Rubicon's acts of infringement, including an order from this Court ensuring that the effective date of any FDA approval of ANDA No. 214445/S-001 shall not be earlier than the expiration date of the '502 Patent.

PRAYER FOR RELIEF

WHEREFORE, Metacel requests that this Court grant the following relief:

- A. A judgment pursuant to 35 U.S.C. § 271(e)(2)(A) and the Hatch-Waxman Act that Rubicon has infringed one or more claims of the '502 Patent by submitting ANDA No. 214445/S-001 to the FDA to obtain approval to manufacture, use, and sell Rubicon's supplemental ANDA Product before the expiration of the '502 Patent.
- B. A judgment pursuant to 35 U.S.C. § 271(a), (b) and/or (c) that Rubicon's making, using, offering for sale, or selling in the United States, or importing into the United States Rubicon's supplemental ANDA Product will infringe one or more claims of the '502 Patent.
- C. A judgment that the '502 Patent is valid and enforceable.
- D. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 214445/S-001 shall not be earlier than the expiration date of the '502 Patent, including any extensions and/or additional periods of exclusivity to which Metacel is or becomes entitled.
- E. A permanent injunction restraining and enjoining Rubicon, its officers, agents, attorneys, employees, affiliates, successors, assigns, and all others acting in concert or participation with Rubicon, from engaging in the commercial manufacture, use, offer for sale, sale, or importation of Rubicon's supplemental ANDA Product within or into the United States until after the expiration date of the '502 Patent, including any extensions and/or additional periods of exclusivity to which Metacel is or becomes entitled.

- F. An award of damages or other monetary relief to Metacel if Rubicon engages in the commercial manufacture, use, offer for sale, sale, or importation of Rubicon's supplemental ANDA Product in or into the United States before the latest expiration date of the '502 Patent, including any extensions and/or additional periods of exclusivity to which Metacel is or becomes entitled.
- G. An award of damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).
- H. A finding that this is an exceptional case under 35 U.S.C. § 285, entitling Metacel to an award of its reasonable attorneys' fees, costs, and expenses incurred in connection with this action.
- I. Such other and further relief as the Court may deem just and proper.

Dated: February 20, 2025

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LOCAL RULE 11.2 CERTIFICATION

We hereby certify that, to the best of our knowledge, the matter in controversy is related to the following action:

Metacel Pharmaceuticals LLC v. Rubicon Research Private Limited, Civil Action No. 21 cv19463 (EP)(JRA)

U.S. Court of Appeals for the Federal Circuit, *Metacel Pharmaceuticals LLC v. Rubicon Research Private Ltd.*, Case No. 23-2386

February 20, 2025

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LOCAL RULE 201.1 CERTIFICATION

We hereby certify that the above captioned matter is not subject to compulsory arbitration in that Plaintiffs seek, *inter alia*, injunctive relief.

February 20, 2025

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