IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC. and PFIZER IRELAND PHARMACEUTICALS,	)	
Plaintiffs,	)	C.A. No. 1:24-cv-00626-CFC
v.	)	
RUBICON RESEARCH PRIVATE LTD.,	)	
Defendant.	)	

DEFENDANT RUBICON RESEARCH PRIVATE LTD.'S
ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO COMPLAINT

Defendant Rubicon Research Private Ltd. ("Rubicon"), by its undersigned counsel, hereby submits its Answer, Affirmative Defenses, and Counterclaims to the Complaint filed by Pfizer Inc. and Pfizer Ireland Pharmaceuticals (collectively, "Pfizer"), and states as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Rubicon denies all allegations in Plaintiffs' Complaint except those specifically admitted below.

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, arising from Rubicon's submission of Abbreviated New Drug Application ("ANDA") No. 219440 (the "Rubicon ANDA") to the United States Food and Drug Administration ("FDA"), seeking approval to market a generic version of Pfizer's NURTEC ODT® (rimegepant sulfate) tablet before the expiration of U.S. Patent No. 11,083,724 ("the '724 patent" or "the patent-in-suit").

ANSWER: Paragraph 1 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Rubicon admits that Plaintiffs' Complaint purports to set forth an action for infringement arising from Rubicon's submission of Abbreviated New Drug Application ("ANDA") No. 219440 regarding a generic version of Pfizer Inc.'s

NURTEC ODT® (rimegepant sulfate) and related United States Patent No. 11,083,724 ("the '724 patent" or "the patent-in-suit") arising under the patent laws of the United States, Title 35 of the United States Code and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.* Otherwise, denied.

THE PARTIES

2. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 66 Hudson Boulevard East, New York, NY 10001.

ANSWER: Rubicon lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

3. Plaintiff Pfizer Ireland Pharmaceuticals is a private unlimited liability company organized under the laws of Ireland and has its registered office at Operations Support Group, Ringaskiddy, Co. Cork, Ireland. Pfizer Ireland Pharmaceuticals is a wholly owned, indirect subsidiary of Pfizer Inc.

ANSWER: Rubicon lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

4. Upon information and belief, Defendant Rubicon is a company organized and existing under the laws of India, having a principal place of business at MedOne House, B – 75, Road No. 33, Wagle Estate, Thane West – 400604, Maharashtra, India.

ANSWER: Admitted.

5. Upon information and belief, Rubicon is a generic pharmaceutical company that, develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Rubicon admits that it sells pharmaceutical products in the United States. Otherwise, denied.

THE PATENT-IN-SUIT

6. On August 10, 2021, the USPTO duly and legally issued the '724 patent, entitled "Rimegepant for CGRP Related Disorders." The '724 patent is assigned to Pfizer Ireland Pharmaceuticals. A copy of the '724 patent is attached to this Complaint as Exhibit A.

ANSWER: Rubicon admits only that the '724 patent is entitled "Rimegepant for CGRP Related Disorders," issued on August 10, 2021, and that a purported copy thereof was attached as Exhibit A to the Complaint. Rubicon lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph and, therefore, denies those allegations. To the extent that any allegations of this Paragraph require a legal conclusion, Rubicon further denies those allegations.

NURTEC ODT®

7. Pfizer Inc. holds approved New Drug Application No. 212728 for rimegepant sulfate orally disintegrating tablets (trade name NURTEC ODT®) for the acute treatment of migraine with or without aura in adults and the preventive treatment of episodic migraine in adults.

ANSWER: Rubicon lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations, but admits that information published by FDA identifies Pfizer Inc. as the holder of New Drug Application ("NDA") No. 212728.

8. Pursuant to 21 U.S.C. § 355(c)(2), and attendant FDA regulations, the patent-in-suit is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to NURTEC ODT®.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Rubicon lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations, but admits that the patent-in-suit is listed in the "Orange Book" with respect to NURTEC ODT®.

THE RUBICON ANDA

9. Upon information and belief, Rubicon prepared and submitted the Rubicon ANDA to the FDA in accordance with 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of rimegepant sulfate orally disintegrating tablets ("Rubicon's ANDA Product") before the expiration of the patent-in-suit.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Rubicon admits that it submitted Rubicon's ANDA to the FDA seeking approval for Rubicon's ANDA Product. Otherwise, denied.

10. Upon information and belief, Rubicon's ANDA Product is a generic copy of NURTEC ODT®.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Rubicon admits that Rubicon's ANDA Product will use rimegepant sulfate as an active ingredient. Otherwise, denied.

11. Upon information and belief, the Rubicon ANDA refers to and relies upon Pfizer's New Drug Application No. 212728 and purports to contain data on the bioequivalence of Rubicon's ANDA Product to NURTEC ODT®.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Rubicon admits that the Rubicon ANDA references New Drug Application 212728 and addresses bioequivalence of Rubicon's ANDA Product. Otherwise, denied.

12. By a letter to Pfizer Inc., Pfizer Ireland Pharmaceuticals, Biohaven Pharmaceuticals, Inc., Biohaven Pharmaceutical Ireland DAC, and Biohaven Pharmaceutical Holding Company Ltd., dated April 10, 2024 ("Rubicon's Paragraph IV Notice Letter"), Rubicon stated that the Rubicon ANDA contained a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that no valid and enforceable claim of the patent-in-suit will be infringed by the manufacture, use, or sale of Rubicon's ANDA Product (the "Paragraph IV Certification"). Rubicon's Paragraph IV Notice Letter included a statement purporting to allege the factual and legal bases for the Paragraph IV Certification.

ANSWER: Admitted.

13. Upon information and belief, if the FDA approves the Rubicon ANDA, Rubicon will manufacture, distribute, import, offer for sale and/or sell Rubicon's ANDA Product throughout the United States, including within the State of Delaware.

ANSWER: Rubicon lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

14. This action is being filed within 45 days of Pfizer's receipt of Rubicon's Paragraph IV Notice Letter.

ANSWER: Admitted.

JURISDICTION AND VENUE

15. This case arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Rubicon does not contest that the Court has subject matter jurisdiction over this action for the purposes of the instant case, but only to the extent each Plaintiff has standing to bring the claims set forth in the complaint.

16. This Court has personal jurisdiction over Rubicon because, inter alia, it has purposefully availed itself of the privileges and benefits of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Rubicon is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Rubicon directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and Delaware. By continuously placing its products into the stream of commerce for distribution and consumption in Delaware, Rubicon's contacts with Delaware have been systematic and continuous, and this judicial district is a likely destination of Rubicon's ANDA Product.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Rubicon does not contest that this Court has personal jurisdiction over Rubicon for purposes of this action only.

17. Upon information and belief, Rubicon prepared and submitted the Rubicon ANDA, with the intention of receiving a significant financial benefit from the FDA's approval of the Rubicon ANDA.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, denied.

18. For these and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Rubicon.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Rubicon does not contest that this Court has personal jurisdiction over Rubicon for purposes of this action only.

19. Venue is proper in this Court for Rubicon under 28 U.S.C. § 1391 because, upon information and belief, Rubicon is not a resident of the United States and may thus be sued in any judicial district.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, solely for the purposes of this action, Rubicon is not contesting Plaintiffs' choice of venue. Otherwise, denied.

COUNT I
(Infringement of the '724 Patent)

20. Pfizer realleges, and incorporates fully herein, each preceding paragraph.

ANSWER: Rubicon restates, realleges, and incorporates by reference fully herein each of the responses to each preceding Paragraph.

21. Defendant has infringed one or more claims of the '724 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining the Rubicon ANDA, by which Defendant seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Rubicon's ANDA Product before the expiration of the '724 patent.

ANSWER: Denied.

22. Upon information and belief, Defendant's commercial manufacture, sale, offer for sale, or use of Rubicon's ANDA Product within the United States, or importation of Rubicon's ANDA Product into the United States, during the term of the '724 patent would infringe one or more claims of the '724 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Denied.

23. Upon information and belief, Defendant's commercial manufacture, sale, offer for sale, or use of Rubicon's ANDA Product within the United States, or importation of Rubicon's ANDA Product into the United States, during the term of the '724 patent would induce and/or contribute to the infringement of one or more claims of the '724 patent under 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Denied.

24. For example, claim 1 of the '724 patent recites:

> A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of a CGRP receptor antagonist, or a pharmaceutically acceptable salt thereof, wherein the pharmaceutical composition is in a form of an oral solid molded fast-dispersing dosage form.

ANSWER: Rubicon admits that claim 1 of the '724 patent recites the quotation provided in this Paragraph.

25. Upon information and belief, Rubicon's ANDA Product will contain a pharmaceutical composition comprising a therapeutically effective amount of rimegepant sulfate, which is a pharmaceutically acceptable salt of the CGRP receptor antagonist rimegepant. Upon information and belief, the pharmaceutical composition of Rubicon's ANDA Product will be in a form of an oral solid molded fast-dispersing dosage form.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Rubicon lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

26. Upon information and belief, Defendant has acted with full knowledge of the '724 patent and without a reasonable basis for believing that it would not be liable for infringement of the '724 patent. Notwithstanding this knowledge, Defendant has continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Rubicon's ANDA Product with its proposed labeling immediately and imminently upon approval of the Rubicon ANDA. Upon information and belief, through such activities, Defendant specifically intends infringement of the '724 patent.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Rubicon admits that it was aware of the '724 patent as of the date of the filing of its ANDA. Otherwise, denied.

27. Upon information and belief, if the FDA approves the Rubicon ANDA, Defendant plans and intends to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '724 patent, and will do so immediately and imminently upon approval.

ANSWER: Denied.

28. Upon information and belief, Defendant knows that Rubicon's ANDA Product is especially made or adapted for use in infringing the '724 patent, and that Rubicon's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to infringement of the '724 patent immediately and imminently upon approval of the Rubicon ANDA.

ANSWER: Denied.

29. Pfizer will be harmed substantially and irreparably if the Defendant is not enjoined from infringing the '724 patent.

ANSWER: Denied.

30. Pfizer has no adequate remedy at law.

ANSWER: Denied.

31. Pfizer is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

COUNT II
(Declaratory Judgment of Infringement of the '724 Patent)

32. Pfizer realleges, and incorporates fully herein, each preceding paragraph.

ANSWER: Rubicon restates, realleges, and incorporates by reference fully herein each of the responses to each preceding Paragraph.

33. There is a substantial and immediate controversy between Pfizer and Rubicon concerning the '724 patent. Pfizer is entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Rubicon will infringe, actively induce infringement of, and/or contribute to the infringement of the '724 patent upon approval of the Rubicon ANDA.

ANSWER: Denied.

34. Upon information and belief, Defendant's commercial manufacture, sale, offer for sale, or use of Rubicon's ANDA Product within the United States, or importation of Rubicon's ANDA Product into the United States, during the term of the '724 patent would infringe one or more claims of the '724 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Denied.

35. Upon information and belief, Defendant's commercial manufacture, sale, offer for sale, or use of Rubicon's ANDA Product within the United States, or importation of Rubicon's ANDA Product into the United States, during the term of the '724 patent would induce and/or contribute to the infringement of one or more claims of the '724 patent under 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Denied.

36. For example, claim 1 of the '724 patent recites:

> A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of a CGRP receptor antagonist, or a pharmaceutically acceptable salt thereof, wherein the pharmaceutical composition is in a form of an oral solid molded fast-dispersing dosage form.

ANSWER: Rubicon admits that claim 1 of the '724 patent recites the quotation provided in this Paragraph.

37. Upon information and belief, Rubicon's ANDA Product will contain a pharmaceutical composition comprising a therapeutically effective amount of rimegepant sulfate, which is a pharmaceutically acceptable salt of the CGRP receptor antagonist rimegepant. Upon information and belief, the pharmaceutical composition of Rubicon's ANDA product will be in a form of an oral solid molded fast-dispersing dosage form.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Rubicon lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

38. Upon information and belief, the Defendant has acted with full knowledge of the '724 patent and without a reasonable basis for believing that they would not be liable for infringement of the '724 patent. Notwithstanding this knowledge, Defendant has continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Rubicon's ANDA Product with its proposed labeling immediately and imminently upon approval of the Rubicon ANDA. Upon information and belief, through such activities, Defendant specifically intends infringement of the '724 patent.

ANSWER: This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Rubicon admits that it was aware of the '724 patent as of the date of the filing of its ANDA. Otherwise, denied.

39. Upon information and belief, if the FDA approves the Rubicon ANDA, Defendant plans and intends to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '724 patent, and will do so immediately and imminently upon approval.

ANSWER: Denied.

40. Upon information and belief, Defendant knows that Rubicon's ANDA Product is especially made or adapted for use in infringing the '724 patent, and that Rubicon's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to infringement of the '724 patent immediately and imminently upon approval of the Rubicon ANDA.

ANSWER: Denied.

41. Pfizer will be harmed substantially and irreparably if the Defendant is not enjoined from infringing the '724 patent.

ANSWER: Denied.

42. Pfizer has no adequate remedy at law.

ANSWER: Denied.

43. Pfizer is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

44. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Rubicon's ANDA Product with its proposed labeling will infringe the '724 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

PRAYER FOR RELIEF

WHEREFORE, Pfizer prays for a judgment in their favor and against the Defendant and respectfully requests the following relief:

A. A judgment that the Defendant has infringed the patent-in-suit pursuant to 35 U.S.C. § 271(e)(2)(A) by submitting to the FDA and maintaining ANDA No. 219440;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of approval of ANDA No. 219440 shall be a date not earlier than the expiration of the patent-in-suit, or any later expiration of exclusivity to which Pfizer is or becomes entitled;

C. A judgment declaring that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Rubicon's ANDA Product will directly infringe, induce and/or contribute to infringement of the patent-in-suit;

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining the Defendant, its officers, agents, servants, and employees, and those persons acting in privity or concert with the Defendant, from manufacturing, using, offering to sell, or selling Rubicon's ANDA Product within the United States, or importing Rubicon's ANDA Product into the United States, before the expiration of the patent-in-suit, or any later expiration of exclusivity to which Pfizer is or becomes entitled;

E. If Defendant commercially manufactures, uses, offers to sell, or sells Rubicon's ANDA Product within the United States, or imports Rubicon's ANDA Product into the United States, before the expiration of the patent-in-suit, including any extensions, a judgment awarding damages to Pfizer resulting from such infringement, together with interest;

F. A judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Pfizer their attorneys' fees incurred in this action;

G. A judgment awarding Pfizer costs and expenses incurred in this action; and

H. Such further and other relief as this Court may deem just and proper.

ANSWER: All remaining allegations not specifically admitted herein are denied. It is further denied that Plaintiffs are entitled to the relief requested in the Complaint or to any relief whatsoever.

RUBICON'S AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer, and without admitting any allegations of the Complaint not expressly admitted, Rubicon asserts the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest with Plaintiffs.

FIRST AFFIRMATIVE DEFENSE

Plaintiffs have failed to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The claims of the patent-in-suit is invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103, 112, and/or obviousness-type double patenting.

THIRD AFFIRMATIVE DEFENSE

Rubicon has not and will not directly or indirectly infringe any valid or enforceable claim of the patent-in-suit. The manufacture, use, offer for sale, sale, and/or importation of the products that are the subject of the Rubicon ANDA does not and will not infringe any valid or enforceable claim of the patent-in-suit, either literally or under the doctrine of equivalents.

FOURTH AFFIRMATIVE DEFENSE

Plaintiffs are barred from asserting infringement based on the doctrine of equivalents in view of prosecution history estoppel, disclaimer, the disclosure-dedication rule, vitiation, and/or ensnarement.

FIFTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim for exceptional case or willful infringement.

SIXTH AFFIRMATIVE DEFENSE

35 U.S.C. § 288 prevents Plaintiffs from recovering any costs associated with this case.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiff's Complaint lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a), (b), (c), and/or (g).

EIGHTH AFFIRMATIVE DEFENSE

One or more Plaintiffs lack standing to bring and maintain this lawsuit against Rubicon.

NINTH AFFIRMATIVE DEFENSE

Rubicon reserves all defenses, in law or equity, which may now exist or, in the future, be available during discovery and further factual investigation in this case.

RUBICON'S COUNTERCLAIMS

Without admitting any of the allegations of Pfizer Inc. and Pfizer Ireland Pharmaceuticals (collectively, "Pfizer" or "Plaintiffs/Counterclaim-Defendants"), other than those expressly admitted herein, and without prejudice to the right of Rubicon Research Private Ltd. ("Rubicon") to plead additional Counterclaims as the facts of the matter warrant, Rubicon hereby asserts the following Counterclaims against Counterclaim-Defendants.

1. This is a counterclaim action for declaratory judgment that United States Patent No. 11,083,724 ("the '724 patent" or "the patent-in-suit") is invalid and not infringed pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.,* and for such other relief as the Court deems just and proper.

THE PARTIES

2. Rubicon is a company organized and existing under the laws of India, having a principal place of business at MedOne House, B – 75, Road No. 33, Wagle Estate, Thane West – 400604, Maharashtra, India.

3. On information and belief, and based on the allegations in the Complaint, Plaintiff/Counterclaim-Defendant Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 66 Hudson Boulevard East, New York, New York 10001.

4. On information and belief, and based on the allegations in the Complaint, Plaintiff/Counterclaim-Defendant Pfizer Ireland Pharmaceuticals is a private unlimited liability company organized under the laws of Ireland and has its registered office at Operations Support Group, Ringaskiddy, Co. Cork, Ireland, and is a wholly owned, indirect subsidiary of Plaintiff/Counterclaim-Defendant Pfizer Inc.

JURISDICTION AND VENUE

5. The Court has jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*

6. This is an action based on an actual controversy between Rubicon and Plaintiffs/Counterclaim-Defendants concerning the noninfringement and invalidity of the patent-in-suit arising under the patent laws of the United States, 35 U.S.C. 19 §§ 100 *et seq.*, and Rubicon's right to continue to seek approval by the Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 219440 (the "Rubicon ANDA") and, upon FDA approval, to manufacture, use, sell, and offer to sell within, and/or import into, the United States the product that is the subject of the Rubicon ANDA ("Rubicon's ANDA Product") should Rubicon decide to do so.

7. The Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because they have availed themselves of the rights and privileges, and subjected themselves to the jurisdiction, of this forum by suing Rubicon in this District and, on information and belief, because Plaintiffs/Counterclaim-Defendants transact business within the State of Delaware and/or have engaged in systematic and continuous business contacts—directly or indirectly through a subsidiary—within the State of Delaware.

8. Venue is proper in this District under 28 U.S.C. § 1391, § 1400(b), 21 U.S.C. § 355(j)(5)(C)(i)(II), and/or by Plaintiffs/Counterclaim-Defendants' choice of forum.

BACKGROUND

9. Rubicon incorporates each of its responses to each Paragraph of the Complaint, as well as the foregoing paragraphs 1 through 8 of the Counterclaims, as if fully set forth herein.

10. On or about August 10, 2021, according to the electronic records of the USPTO, the '724 patent, entitled "RIMEGEPANT FOR CGRP RELATED DISORDERS," issued, on its face, with named inventors Vladimir Coric and Robert Croop. Plaintiffs/Counterclaim-Defendants represented that a copy of the '724 patent was attached as Exhibit A to the Complaint. The '724 patent is subject to a terminal disclaimer.

11. On information and belief, one or more of Plaintiffs/Counterclaim-Defendants purport(s) to own, and/or to have the rights to enforce, the patent-in-suit.

12. On information and belief, Plaintiffs/Counterclaim-Defendants caused the FDA to list the patent-in-suit in the FDA's Orange Book publication in connection with New Drug Application ("NDA") No. 212728 for NURTEC ODT®.

13. On information and belief, Plaintiffs/Counterclaim-Defendants have not caused the FDA to remove the patent-in-suit from the Orange Book in connection with NURTEC ODT®.

14. By maintaining that listing of the patent-in-suit in the Orange Book, Plaintiffs/Counterclaim-Defendants represent that the claims of infringement of the patent-in-suit "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *See* 21 U.S.C. § 355(b)(1)(A)(viii).

15. By a letter dated April 10, 2024 ("Rubicon's Paragraph IV Notice Letter"), Rubicon timely notified Plaintiffs/Counterclaim-Defendants that the Rubicon ANDA contained a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the patent-in-suit ("Notice Letter"). Rubicon's Notice Letter met the statutory and regulatory requirements for such notice letters and included a detailed statement of the factual and legal bases for Rubicon's opinion that the claims of the patent-in-suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, and/or importation of Rubicon's ANDA Product. Rubicon

incorporates by reference the positions set forth in its Notice Letter but reserves the right to amend them.

16. Rubicon's Notice Letter included an Offer of Confidential Access ("OCA"), provided pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). Despite providing this OCA, on information and belief, counsel for Rubicon is unaware of any attempt by Plaintiffs/Counterclaim-Defendants to negotiate the terms of the OCA or otherwise seek access to Rubicon's ANDA in order to make a determination as to whether an infringement action should be brought.

17. On May 23, 2024, without reviewing any portions of Rubicon's ANDA, Plaintiffs/Counterclaim-Defendants sued Rubicon in this District for purported infringement of the patent-in-suit.

18. In view of the foregoing, there has been, and is now, a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between Rubicon and Plaintiffs/Counterclaim-Defendants having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court with respect to noninfringement and invalidity of the patent-in-suit, and as to Rubicon's right to obtain FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Rubicon's ANDA Product.

COUNT I
(Declaratory Judgment of Noninfringement of the '724 Patent)

19. Rubicon incorporates each of its responses to each Paragraph of the Complaint, as well as the foregoing paragraphs 1 through 18 of the Counterclaims, as if fully set forth herein.

20. There is an actual, substantial, and continuing justiciable case or controversy between Rubicon and Plaintiffs/Counterclaim-Defendants regarding whether the manufacture, use, offer for sale, sale, or importation of Rubicon's ANDA Product will infringe any claim of the '724 patent.

21. Rubicon denies infringement of any valid, enforceable, and properly construed claim of the '724 patent and alleges that Rubicon has not, does not, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, and properly construed claim of the '724 patent, including for at least the reasons set forth in the detailed statement included with Rubicon's Notice Letter.

22. The manufacture, use, sale, or offer for sale within, and/or importation into the United States of Rubicon's ANDA Products does not and will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, and properly construed claim of the '724 patent, including for at least the reasons set forth in the detailed statement included with Rubicon's Notice Letter.

23. Rubicon is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Rubicon's ANDA Products does not and will not infringe any valid and/or enforceable claim of the '724 patent.

COUNT II
(Declaratory Judgment of Invalidity of the '724 Patent)

24. Rubicon incorporates each of its responses to each Paragraph of the Complaint, as well as the foregoing paragraphs 1 through 23 of the Counterclaims, as if fully set forth herein.

25. Plaintiffs/Counterclaim-Defendants have accused Rubicon of infringing claims of the '724 patent in connection with ANDA No. 219440.

26. Rubicon denies infringement of any claim of the '724 patent because all claims of the '724 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code. Given their invalidity, Rubicon cannot infringe any

claims of the '724 patent, including for at least the reasons set forth in the detailed statement included with Rubicon's Notice Letter.

27. The alleged inventions of the '724 patent do no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '724 patent is no more than the predictable use of prior art elements. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged inventions of the '724 patent and would have had a reasonable expectation of success in doing so.

28. The claims of the '724 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art. The differences between the subject matter claimed in the '724 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious, at the time that the alleged inventions were made, to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

29. Unless Plaintiffs/Counterclaim-Defendants are enjoined, Rubicon believes that Plaintiffs/Counterclaim-Defendants will continue to assert that Rubicon infringes the claims of the '724 patent and will continue to interfere with Rubicon's business.

30. Rubicon will be irreparably harmed if Plaintiffs/Counterclaim-Defendants are not enjoined from continuing to assert the claims of the '724 patent and from interfering with Rubicon's business.

31. Rubicon is entitled to a declaratory judgment that the asserted claims of the '724 patent are invalid.

EXCEPTIONAL CASE

This case is an exceptional one and Rubicon is entitled to an award of its reasonable attorneys' fees and costs under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Rubicon prays that the Court enter judgment in its favor and against Plaintiffs/Counterclaim-Defendants as follows:

a) Dismissing the Complaint with prejudice and denying each request for relief made by Plaintiffs/Counterclaim-Defendants therein;

b) Declaring that the claims of the patent-in-suit are not and will not be infringed either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the patent-in-suit;

c) Declaring that the claims of the patent-in-suit are invalid or unenforceable for failure to comply with one or more provisions of 35 U.S.C. § 101, *et seq.* including, *inter alia*, §§ 102, 103, and 112;

d) Entering judgment in Rubicon's favor;

e) Finding that this case is exceptional pursuant to 35 U.S.C. § 285 and granting an award of Rubicon's attorneys' fees and costs to the extent permitted by law; and

f) Granting Rubicon any and all other relief to which Rubicon may be justly entitled.

Dated: July 29, 2024

/s/ Kenneth L. Dorsney

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