IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC. and PFIZER IRELAND PHARMACEUTICALS,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
RUBICON RESEARCH PRIVATE LTD.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Pfizer Inc. and Pfizer Ireland Pharmaceuticals (collectively, "Pfizer"), by their undersigned attorneys, for their Complaint against defendant Rubicon Research Private Ltd. ("Rubicon"), allege as follows:

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").

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.

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.

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.

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.

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.

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.

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®.

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.

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

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®.

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.

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.

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

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.

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.

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.

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

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.

COUNT I
(Infringement of the '724 Patent)

20. Pfizer realleges, and incorporates fully herein, 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.

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.

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).

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.

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.

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.

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.

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.

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

30. Pfizer has no adequate remedy at law.

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.

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

32. Pfizer realleges, and incorporates fully herein, 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.

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.

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).

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.

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.

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.

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.

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.

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

42. Pfizer has no adequate remedy at law.

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.

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).

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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

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