IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PIERRE FABRE MEDICAMENT SAS, UNIVERSITÉ DE BORDEAUX, CENTRE HOSPITALIER UNIVERSITAIRE DE BORDEAUX, and PIERRE FABRE PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	C.A. No. 24-811 (JLH)
v.	)	
RUBICON RESEARCH PRIVATE LIMITED,	)	
Defendant.	)	

DEFENDANT RUBICON RESEARCH PRIVATE LIMITED'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT

Defendant Rubicon Research Private Limited ("Rubicon" or "Defendant"), by and through its undersigned counsel, files this Answer, Affirmative Defenses, and Counterclaims to Plaintiffs Pierre Fabre Medicament SAS ("Pierre Fabre"); Université de Bordeaux ("Bordeaux"); Centre Hospitalier Universitaire de Bordeaux ("CHU"); and Pierre Fabre Pharmaceuticals, Inc.'s ("PFPI") (collectively, "Plaintiffs") Complaint for Patent Infringement (D.I. 1), and states as follows:

GENERAL DENIAL

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

NATURE OF ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, U.S. Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 that arises out of Defendant's submission of Abbreviated New Drug Application ("ANDA") No. 219574 to the U.S. Food and

Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, and/or import versions of Pierre Fabre's HEMANGEOL (Propranolol Hydrochloride) Solution; Oral, 4.28 MG/ML that is the subject of New Drug Application ("NDA") No. N205410 ("HEMANGEOL") prior to the expiration of U.S. Patent Nos. 8,338,489 ("the '489 Patent") and 8,987,262 ("the '262 Patent") (together, the "Asserted Patents"). Plaintiffs seek all available relief under 35 U.S.C. § 100 *et seq.*, 28 U.S.C. §§ 2201 and 2202, and all other applicable laws for Rubicon's infringement of the Asserted Patents.

ANSWER: Rubicon admits that Plaintiffs filed a civil action alleging that Rubicon infringes U.S. Patent Nos. 8,338,489 ("the '489 Patent") and 8,987,262 ("the '262 Patent") (together, the "Asserted Patents") under the patent laws of the United States, Title 35 of the United States Code. Rubicon admits that it had filed Abbreviated New Drug Application ("ANDA") No. 219574 with the U.S. Food and Drug Administration ("FDA") that references NDA No. N205410. Except as expressly admitted, Rubicon denies the remaining allegations of Paragraph 1.

2. Defendant notified Plaintiffs by letter dated May 29, 2024 ("Rubicon's Notice Letter") that it had submitted to the FDA ANDA No. 219574 ("Rubicon's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of generic propranolol hydrochloride solution for oral use ("Rubicon's ANDA Product") prior to the expiration of the asserted patents.

ANSWER: Rubicon admits that it sent a notice letter to Plaintiffs dated May 29, 2024. The content of Rubicon's Notice Letter speaks for itself. Except as expressly admitted, Rubicon denies the remaining allegations of Paragraph 2.

3. On information and belief, Rubicon's ANDA Product is a generic version of Plaintiff's HEMANGEOL product.

ANSWER: Paragraph 3 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon admits that Rubicon's ANDA references NDA No. N205410. Except as expressly admitted, Rubicon denies the remaining allegations of Paragraph 3.

THE PARTIES

4. Plaintiff Pierre Fabre is a French corporation having a principal place of business at Les Cauquillous, 81500 Lavaur, France.

ANSWER: On information and believe, Rubicon admits the allegations of Paragraph 4.

5. Plaintiff Bordeaux is a French nonprofit Research and Educational Public Institution (Etablissement Public à caractère Scientifique, Culturel et Professionnel) having a principal place of business at 35, Place Pey Berland, 33000 Bordeaux, France.

ANSWER: On information and believe, Rubicon admits the allegations of Paragraph 5.

6. Plaintiff CHU is a French nonprofit Healthcare Public Institution (Etablissement Public de Santé) having a principal place of business at 12 Rue Dubernat, 33404 Talence, France.

ANSWER: On information and believe, Rubicon admits the allegations of Paragraph 6.

7. Plaintiff PFPI is a Delaware corporation having a principal place of business at 8 Campus Drive, Parsippany, New Jersey 07054.

ANSWER: On information and believe, Rubicon admits the allegations of Paragraph 7.

8. On information and belief, Defendant Rubicon is an Indian corporation with a principal place of business at MedOne House, Plot No. B-75, Road No. 33, Wagle Estate, Thane West 400604, Maharashtra, India.

ANSWER: Admitted.

9. On information and belief, Rubicon's business includes developing, manufacturing, marketing, importing, and selling generic copies of innovator pharmaceutical products for the United States market.

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon admits that it develops and manufactures high-quality generic pharmaceutical products, some of which are ultimately used by consumers in the United States. Except as expressly admitted, Rubicon denies the remaining allegations of Paragraph 9.

JURISDICTION AND VENUE

10. This patent infringement action arises under the United States Patent Act, codified at Title 35, U.S. Code, and as an action for declaratory judgment under 28 U.S.C. §§ 2201 and 2202 arising from Defendant's submission of Rubicon's ANDA.

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon admits that Plaintiffs purport to bring this action under the United States Patent Code, 35 U.S.C. § 100 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Except as expressly admitted, Rubicon denies the remaining allegations of Paragraph 10.

11. This Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Relief is sought under 35 U.S.C. § 271(e)(2).

ANSWER: Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon admits that this Court has subject matter jurisdiction over this Action under 28 U.S.C. §§ 1331 and 1338(a) for Plaintiffs' claims under 35 U.S.C. § 271(e)(2). Rubicon denies the remaining allegations of Paragraph 11.

12. This Court has personal jurisdiction over Rubicon because, on information and belief, Rubicon maintains persistent and continuous contacts with Delaware and has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Rubicon regularly and continuously develops, manufactures, markets, and/or sells generic pharmaceutical products in Delaware and derives substantial revenue from the sale of those products in Delaware.

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Rubicon denies the remaining allegations of Paragraph 12.

13. Additionally, on information and belief, Delaware is a likely destination of the product that is the subject of ANDA No. 219574.

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 13.

14. Alternatively, this Court has personal jurisdiction over Rubicon under FED. R. CIV. P. 4(k)(2) because Plaintiffs' claims arise under federal law; Rubicon is a foreign defendant not subject to personal jurisdiction in the courts of any state; and Rubicon has sufficient contacts with the United States as a whole, including at least preparing and submitting ANDA No. 219574 to the FDA and manufacturing, importing, offering to sell, and/or selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Rubicon satisfies due process.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Rubicon denies the remaining allegations of Paragraph 14.

15. Venue in this District is proper under 28 U.S.C. §§ 1391(b) and (c) because Rubicon is a foreign corporation not residing in any state and therefore may be sued in any judicial district having personal jurisdiction over Rubicon.

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon does not contest venue in this Court for the limited purposes of this action only. Except as expressly admitted, Rubicon denies the remaining allegations of Paragraph 15.

PIERRE FABRE'S HEMANGEOL PRODUCT

16. Pierre Fabre is the holder of NDA No. N205410.

ANSWER: Rubicon admits that the United States Food & Drug Administration's ("FDA's") publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") lists Pierre Fabre as the holder of NDA No. N205410.

17. Pierre Fabre's HEMANGEOL, covered by NDA No. N205410, is the only FDA approved treatment for infantile hemangioma requiring systemic therapy.

ANSWER: Rubicon is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 17 and therefore denies the allegations.

18. PFPI is exclusively responsible for sales of HEMANGEOL in the United States.

ANSWER: Rubicon is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 18 and therefore denies the allegations.

19. Plaintiffs Bordeaux and CHU are the assignees of all rights from the named inventors to the Asserted Patents, as reflected in the assignments recorded at Reel 024381, Frame 0618; Reel 033025, Frame 0790; Reel 033025, Frame 0881; and Reel 029684, Frame 0737.

ANSWER: Rubicon admits that, on information and belief, publicly available electronic records of the United States Patent Office ("PTO") indicate that Plaintiffs Bordeaux and CHU are assignees of the Asserted Patents. Except as expressly admitted, Rubicon denies the remaining allegations of Paragraph 19.

20. Pierre Fabre is the exclusive licensee to all rights under the Asserted Patents, as reflected in documents recorded at Reel 064782, Frame 0285.

ANSWER: Rubicon admits that, on information and belief, publicly available electronic records of the PTO indicate that Pierre Fabre is a licensee of the Asserted Patents. Except as expressly admitted, Rubicon denies the remaining allegations of Paragraph 20.

THE ASSERTED PATENTS

21. On November 6, 2009, Christine Léauté-Labrèze, Eric Dumas De La Roque, Alain Taïeb, and Jean-Benoît Thambo ("the Inventors") filed U.S. Patent Application No. 12/599,266 ("the '266 Application") entitled "Use of a Beta Blocker for the Manufacture of a Medicament for the Treatment of Hemangiomas."

ANSWER: Rubicon admits that U.S. Patent Application No. 12/599,266 ("the '266 Application") is entitled "Use of a Beta Blocker for the Manufacture of a Medicament for the Treatment of Hemangiomas." Except as expressly admitted, Rubicon denies the remaining allegations of Paragraph 21.

22. The ’266 Application is the national stage entry into the United States of PCT Patent Application No. PCT/IB2008/002746, filed on October 16, 2008, and claims priority to Provisional Patent Application No. 60/989,507, filed on November 21, 2007; and European Patent Application No. 07291723.6, filed on October 19, 2007.

ANSWER: Rubicon is without sufficient knowledge or information to form a belief as to the allegations of Paragraph 22 and therefore denies the allegations.

23. On December 25, 2012, the ’489 Patent was issued by the PTO based on the ’266 Application. A true and correct copy of the ’489 Patent is attached hereto as Exhibit A and is incorporated by reference as if fully set forth herein.

ANSWER: Rubicon admits that the ’489 patent was issued by the PTO on or about December 25, 2012. What appears to be an uncertified copy of the ’489 patent was attached to Plaintiffs’ Complaint as Exhibit A. Except as expressly admitted, Rubicon denies the remaining allegations of Paragraph 23.

24. On November 16, 2012, the Inventors filed U.S. Patent Application No. 13/678,802 (“the ’802 Application”) entitled “Use of a Beta Blocker for the Manufacture of a Medicament for the Treatment of Hemangiomas.”

ANSWER: Rubicon admits that, on information and belief, according to publicly available information, U.S. Patent Application No. 13/678,802 (“the ’802 Application”) was filed on November 16, 2012, and is entitled “Use of a Beta Blocker for the Manufacture of a Medicament for the Treatment of Hemangiomas.” Except as expressly admitted, Rubicon denies the remaining allegations of Paragraph 24.

25. The ’802 Application was filed as a continuation-in-part of the ’266 Application, which was filed as the national stage entry of PCT Patent Application No. PCT/IB2008/002746, filed on October 16, 2008, and further claims priority to Provisional Patent Application No. 60/989,507, filed on November 21, 2007; and European Patent Application No. 07291723.6, filed on October 19, 2007.

ANSWER: Rubicon admits that the face of the ’262 patent indicates that the ’802 Application is a Continuation-In-Part of the ’266 Application. Rubicon is without sufficient

knowledge or information to form a belief as to the remaining allegations of Paragraph 25 and on that basis denies the allegations.

26. On March 24, 2015, the '262 Patent was issued by the PTO based on the '802 Application. A true and correct copy of the '262 Patent is attached hereto as Exhibit B and is incorporated by reference as if fully set forth herein.

ANSWER: Rubicon admits that the '262 patent was issued by the PTO on or about March 24, 2015. What appears to be an uncertified copy of the '262 patent was attached to Plaintiffs' Complaint as Exhibit B. Except as expressly admitted, Rubicon denies the remaining allegations of Paragraph 26.

27. The Asserted Patents are valid and enforceable.

ANSWER: Paragraph 27 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 27.

28. Pursuant to 21 U.S.C. § 355, the Asserted Patents are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. N205410, sold under the brand name HEMANGEOL.

ANSWER: Rubicon admits that the Asserted Patents are listed in the Orange Book in connection with NDA No. N205410. Except as expressly admitted, Rubicon is without knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 28, and on that basis denies these allegations.

29. Pierre Fabre's HEMANGEOL product is covered by at least one claim of each of the Asserted patents.

ANSWER: Paragraph 29 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 29.

30. Plaintiff Pierre Fabre possesses all rights of recovery under the Asserted Patents, including the right to sue for infringement, recourse for damages, and to seek injunctive relief.

ANSWER: Paragraph 30 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 30.

INFRINGEMENT BY RUBICON

31. In Rubicon's Notice Letter, Rubicon notified Pierre Fabre, Bordeaux, CHU, and Pierre Fabre Dermatologie that it had submitted ANDA No. 219574 to the FDA pursuant to subsection 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act ("the FDCA") (21 U.S.C. § 355(j)(2)(B)) to obtain approval to engage in the commercial manufacture, use, or sale of a generic version of Pierre Fabre's HEMANGEOL product, Rubicon's ANDA Product, before the expiration of the Asserted Patents.

ANSWER: Rubicon admits that it sent a notice letter to Plaintiffs. The content of Rubicon's Notice Letter speaks for itself. Except as expressly admitted, Rubicon denies the remaining allegations of Paragraph 31.

32. The Asserted Patents will expire shortly after midnight on October 16, 2028.

ANSWER: Paragraph 32 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon admits that the Orange Book lists the expiration dates of the Asserted Patents as October 16, 2028. Except as expressly admitted, Rubicon denies the allegations of Paragraph 32.

33. On information and belief, Rubicon intends to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the Rubicon ANDA Product promptly upon receiving FDA approval to do so.

ANSWER: Paragraph 33 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 33.

34. Rubicon is seeking approval from the FDA to engage in the commercial manufacture, use, and sale of the Rubicon ANDA Product before the expiration of the Asserted Patents.

ANSWER: Paragraph 34 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon admits that Rubicon's ANDA includes a

certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to each of the Asserted Patents. Except as expressly admitted, Rubicon denies the remaining allegations of Paragraph 34.

35. By submitting ANDA No. 219574, Rubicon necessarily represented to the FDA that Rubicon's ANDA Product has the same active ingredients as Pierre Fabre's HEMANGEOL product; has the same route of administration, dosage form, use, and strength as Pierre Fabre's HEMANGEOL product; and is bioequivalent to Pierre Fabre's HEMANGEOL product.

ANSWER: Paragraph 35 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon admits that Rubicon's ANDA Product is Propranolol Hydrochloride Oral Solution, 4.28 mg/mL. Except as expressly admitted, Rubicon denies the remaining allegations of Paragraph 35.

COUNT I – INFRINGEMENT OF THE '489 PATENT

36. Plaintiffs reallege and incorporate by reference paragraphs 1 through 35 of this Complaint as if fully set forth herein.

ANSWER: Rubicon incorporates and realleges each of its responses to Paragraphs 1 through 35 of the Complaint as if fully set forth herein.

37. Rubicon submitted or caused the submission of ANDA No. 219574 to the FDA under § 505(j) of the FDCA to obtain approval to commercially manufacture, use, offer for sale, sell, and/or import Rubicon's ANDA Product throughout the United States before the expiration of the '489 Patent.

ANSWER: Paragraph 37 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 37.

38. Rubicon's ANDA Product is covered by one or more claims of the '489 Patent.

ANSWER: Paragraph 38 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 38.

39. By submitting ANDA No. 219574, Rubicon committed an act of infringement of one or more claims of the '489 Patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 39 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 39.

40. The claims infringed by Rubicon's ANDA Product include at least Claim 1 of the '489 Patent.

ANSWER: Paragraph 40 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 40.

41. If ANDA No. 219574 is approved, Rubicon's commercial manufacture, use, offering for sale, sale, and/or importation of Rubicon's ANDA Product will constitute acts of infringement, either literally or under the doctrine of equivalents, of the '489 Patent under 35 U.S.C. § 271(a) unless enjoined by the Court.

ANSWER: Paragraph 41 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 41.

42. If ANDA No. 219574 is approved, Rubicon will induce infringement of one or more claims of the '489 Patent under 35 U.S.C. § 271(b) by causing third parties to manufacture, use, offer for sale, sell, and/or import Rubicon's ANDA Product into the United States and will intentionally encourage acts of direct infringement with knowledge of the '489 Patent and knowledge that such acts are infringing, unless enjoined by the Court.

ANSWER: Paragraph 42 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 42.

43. If ANDA No. 219574 is approved, Rubicon will contributorily infringe one or more claims of the '489 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Rubicon's ANDA Product into the United States, unless enjoined by this Court. On information and belief, Rubicon has had and continues to have knowledge that the Rubicon ANDA Product is especially adapted for a use that infringes one or more claims of the '489 Patent and that there is no substantial noninfringing use for the Rubicon ANDA Product.

ANSWER: Paragraph 43 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 43.

44. As a result of Rubicon's infringement of the '489 Patent, Plaintiffs will be damaged to an extent not yet determined and will be caused further irreparable harm for which damages are inadequate.

ANSWER: Paragraph 44 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 44.

COUNT II – INFRINGEMENT OF THE '262 PATENT

45. Plaintiffs reallege and incorporate by reference paragraphs 1 through 35 of the Complaint as if fully set forth herein.

ANSWER: Rubicon incorporates and realleges each of its responses to Paragraphs 1 through 35 of this Complaint as if fully set forth herein.

46. Rubicon submitted or caused the submission of ANDA No. 219574 to the FDA under § 505(j) of the FDCA to obtain approval to commercially manufacture, use, offer for sale, sell, and/or import Rubicon's ANDA Product throughout the United States before the expiration of the '262 Patent.

ANSWER: Paragraph 46 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 46.

47. Rubicon's ANDA Product is covered by one or more claims of the '262 Patent.

ANSWER: Paragraph 47 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 47.

48. By submitting ANDA No. 219574, Rubicon committed an act of infringement of one or more claims of the '262 Patent under 35 U.S.C. § 271(e)(2)(A). The infringed claims include at least Claim 1 of the '262 Patent.

ANSWER: Paragraph 48 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 48.

49. If ANDA No. 219574 is approved, Rubicon's commercial manufacture, use, offering for sale, sale, and/or importation of Rubicon's ANDA Product will constitute acts of infringement, either literally or under the doctrine of equivalents, of the '262 Patent under 35 U.S.C. § 271(a) unless enjoined by the Court.

ANSWER: Paragraph 49 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 49.

50. If ANDA No. 219574 is approved, Rubicon will induce infringement of one or more claims of the '262 Patent under 35 U.S.C. § 271(b) by causing third parties to manufacture, use, offer for sale, sell, and/or import Rubicon's ANDA Product into the United States and will intentionally encourage acts of direct infringement with knowledge of the '262 Patent and knowledge that such acts are infringing, unless enjoined by the Court.

ANSWER: Paragraph 50 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 50.

51. If ANDA No. 219574 is approved, Rubicon will contributorily infringe one or more claims of the '262 Patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Rubicon's ANDA Product into the United States, unless enjoined by this Court. On information and belief, Rubicon has had and continues to have knowledge that Rubicon's ANDA Product is especially adapted for a use that infringes one or more claims of the '489 Patent and that there is no substantial noninfringing use for Rubicon's ANDA Product.

ANSWER: Paragraph 51 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 51.

52. As a result of Rubicon's infringement of the '262 Patent, Plaintiffs will be damaged to an extent not yet determined and will be caused further irreparable harm for which damages are inadequate.

ANSWER: Paragraph 52 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 52.

COUNT III – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '489 PATENT

53. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 44 of this Complaint as if fully set forth herein.

ANSWER: Rubicon incorporates and realleges each of its responses to Paragraphs 1 through 44 of the Complaint as if fully set forth herein.

54. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between the Plaintiffs and Rubicon regarding Rubicon's infringement, active inducement of infringement, and contribution to the infringement by others of the '489 Patent.

ANSWER: Paragraph 54 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 54.

55. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Rubicon's ANDA Product, or any other Rubicon drug product that is covered by or the use of which is covered by the '489 Patent, will infringe, induce infringement of, and contribute to the infringement by others of the '489 Patent, and that the claims of the '489 Patent are valid.

ANSWER: Paragraph 55 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 55.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '262 PATENT

56. Plaintiffs reallege and incorporate by reference paragraphs 1 through 35 and 45 through 52 of this Complaint as if fully set forth herein.

ANSWER: Rubicon incorporates and realleges each of its responses to Paragraphs 1 through 35 and Paragraphs 45 through 52 of the Complaint as if fully set forth herein.

57. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between the Plaintiffs and Rubicon regarding Rubicon's infringement, active inducement of infringement, and contribution to the infringement by others of the '262 Patent.

ANSWER: Paragraph 57 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 57.

58. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Rubicon's ANDA Product, or any other Rubicon drug product that is covered by or the use of which is covered by the '262 Patent, will infringe, induce infringement of, and contribute to the infringement by others of the '262 Patent, and that the claims of the '262 Patent are valid.

ANSWER: Paragraph 58 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Rubicon denies the allegations of Paragraph 58.

PLAINTIFFS' PRAYER FOR RELIEF

All allegations in Plaintiffs' Complaint that are not expressly admitted by Rubicon are denied. Rubicon denies that Plaintiffs are entitled to any of the relief sought in their Prayer for Relief.

RUBICON'S AFFIRMATIVE DEFENSES

Without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not expressly admitted, Rubicon asserts the following Affirmative Defenses to Plaintiffs' Complaint without assuming the burden of proof on any defense that would otherwise rest on Plaintiffs. Rubicon reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery.

FIRST AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,338,489)

The '489 Patent and each of the claims thereof are invalid and/or unenforceable for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 102, 103, and/or 112, or under other judicially-created bases for invalidation, including but not limited to, obviousness-type double patenting.

SECOND AFFIRMATIVE DEFENSE
(No Infringement of U.S. Patent No. 8,338,489)

The manufacture, use, or sale, offer for sale, or importation of the product that is the subject of Rubicon's ANDA No. 219574 has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the '489 Patent.

THIRD AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 8,987,262)

The '262 Patent and each of the claims thereof are invalid and/or unenforceable for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 102, 103, and/or 112, or under other judicially-created bases for invalidation, including but not limited to, obviousness-type double patenting.

FOURTH AFFIRMATIVE DEFENSE
(No Infringement of U.S. Patent No. 8,987,262)

The manufacture, use, or sale, offer for sale, or importation of the product that is the subject of Rubicon's ANDA No. 219574 has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the '262 Patent.

FIFTH AFFIRMATIVE DEFENSE
(Failure to State a Claim for Exceptional Case and/or Willful Infringement)

Plaintiffs' Complaint fails to state a claim for exceptional case and/or willful infringement under 35 U.S.C. § 285 and/or 35 U.S.C. § 271(e)(4). Rubicon's actions in defending this case do not give rise to an exceptional case and/or will infringement.

RESERVATION OF DEFENSES

Rubicon reserves any and all defenses available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

RUBICON'S COUNTERCLAIMS

Defendant/Counterclaim Plaintiff Rubicon Research Private Limited ("Rubicon"), by and through its undersigned counsel, pleads the following counterclaims against Plaintiffs/Counterclaim Defendants Pierre Fabre Medicament SAS ("Pierre Fabre"); Université de

Bordeaux ("Bordeaux"); Centre Hospitalier Universitaire de Bordeaux ("CHU"); and Pierre Fabre Pharmaceuticals, Inc.'s ("PFPI") (collectively, "Plaintiffs/Counterclaim Defendants"):

PARTIES

1. Rubicon is an Indian corporation with a principal place of business at MedOne House, Plot No. B-75, Road No. 33, Wagle Estate, Thane.

2. On information and belief, Pierre Fabre is a French corporation having a principal place of business at Les Cauquillous, 81500 Lavaur, France.

3. On information and belief, Bordeaux is a French nonprofit Research and Educational Public Institution (Etablissement Public à caractère Scientifique, Culturel et Professionnel) having a principal place of business at 35, Place Pey Berland, 33000 Bordeaux, France.

4. On information and belief, CHU is a French nonprofit Healthcare Public Institution (Etablissement Public de Santé) having a principal place of business at 12 Rue Dubernat, 33404 Talence, France.

5. On information and belief, PFPI is a Delaware corporation having a principal place of business at 8 Campus Drive, Parsippany, New Jersey 07054.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over these Counterclaims for Declaratory Judgment pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202; based on an actual controversy between Rubicon, on the one hand, and Plaintiffs/Counterclaim Defendants on the other hand, arising under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*

7. This Court has personal jurisdiction over Plaintiffs/Counterclaim Defendants because, *inter alia*, Plaintiffs/Counterclaim Defendants subjected themselves to the jurisdiction of this Court by filing their Complaint here.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b), and/or by Plaintiffs/Counterclaim Defendants' choice of forum.

FACTUAL BACKGROUND

9. On information and belief, and based on the allegations in the Complaint, Pierre Fabre is the holder of New Drug Application ("NDA") No. N205410 for HEMANGEOL (Propranolol Hydrochloride) Solution; Oral, 4.28 MG/ML, for infantile hemangioma requiring systemic therapy.

10. On information and belief, and based on the allegations in the Complaint, Plaintiffs/Counterclaim Defendants caused the United States Food & Drug Administration ("FDA") to list U.S. Patent Nos. 8,338,489 ("the '489 Patent") and 8,987,262 ("the '262 Patent") (together, the "Asserted Patents"). in \ FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") in connection with NDA No. N205410.

11. The '489 Patent is titled "Use of a Beta Blocker for the Manufacture of a Medicament for the Treatment of Hemangiomas," and the face of the '489 Patent indicates it was issued by the PTO on December 25, 2012. An uncertified copy of the '489 Patent was attached to Plaintiffs'/Counterclaim Defendants' Complaint as Exhibit A. *See* D.I. 1-1.

12. Plaintiffs/Counterclaim Defendants purport and claim to be the owner of, and to have the right to enforce, the '489 patent.

13. The ’262 Patent is titled “Use of a Beta Blocker for the Manufacture of a Medicament for the Treatment of Hemangiomas,” and the face of the ’262 Patent indicates it was issued by the PTO on March 24, 2015. An uncertified copy of the ’262 Patent was attached to Plaintiffs’/Counterclaim Defendants’ Complaint as Exhibit B. *See* D.I. 1-2.

14. Plaintiffs/Counterclaim Defendants purport and claim to be the owner of, and to have the right to enforce, the ’262 patent.

15. Rubicon submitted Abbreviated New Drug Application (“ANDA”) No. 219574 to the FDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Propranolol Hydrochloride Solution; Oral, 4.28 MG/ML (“Rubicon’s ANDA product”). Rubicon’s ANDA No. 219574 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the Asserted Patents.

16. Rubicon sent notice of the certification with respect to the Asserted Patents to Plaintiffs/Counterclaim Defendants on or about May 29, 2024 (“Rubicon’s Notice Letter”), which, based on the filing of Plaintiffs’/Counterclaim Defendants’ Complaint, was received shortly thereafter.

17. On July 12, 2024, Plaintiffs/Counterclaim Defendants filed suit in this Judicial District against Rubicon in connection with ANDA No. 219574 alleging infringement of the Asserted Patents.

18. In view of the foregoing, there has been, and is now, an actual, substantial, and continuing, justiciable controversy 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/or invalidity of the Asserted Patents, 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 U.S. Patent No. 8,338,489)

19. Rubicon incorporates by reference and re-alleges each of the foregoing Paragraphs of Rubicon's Answer and Affirmative Defenses to the Plaintiffs/Counterclaim Defendants Complaint for Patent Infringement and Paragraphs 1-18 of these Counterclaims as if fully set forth herein.

20. Rubicon has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '489 patent.

21. A present, genuine, and justiciable controversy exists between Rubicon, on the one hand, and Plaintiffs/Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Rubicon's ANDA Product would infringe any valid or enforceable claim of the '489 patent.

22. The Court should declare that Rubicon has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '489 patent.

COUNT II
(Declaratory Judgment of Invalidity of U.S. Patent No. 8,338,489)

23. Rubicon incorporates by reference and re-alleges each of the foregoing Paragraphs of Rubicon's Answer and Affirmative Defenses to the Plaintiffs/Counterclaim Defendants Complaint for Patent Infringement and Paragraphs 1-18 of these Counterclaims as if fully set forth herein.

24. Upon information and belief, the claims of the '489 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103 and/or 112 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

25. There is a real, substantial, and justiciable controversy between Rubicon and Plaintiffs/Counterclaim Defendants concerning whether the claims of the '489 patent are invalid and/or unenforceable for failure to comply with one or more of the requirements of Title 35 of the United States Code, including, without limitation, one or more §§ 101, 102, 103 and/or 112 *et seq*. and/or pursuant to common law and/or equitable doctrines.

26. The Court should declare that the claims of the '489 patent are invalid and/or unenforceable.

COUNT III
(Declaratory Judgment of Noninfringement of U.S. Patent No. 8,987,262)

27. Rubicon incorporates by reference and re-alleges each of the foregoing Paragraphs of Rubicon's Answer and Affirmative Defenses to the Plaintiffs/Counterclaim Defendants Complaint for Patent Infringement and Paragraphs 1-18 of these Counterclaims as if fully set forth herein.

28. Rubicon has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '262 patent.

29. A present, genuine, and justiciable controversy exists between Rubicon, on the one hand, and Plaintiffs/Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Rubicon's ANDA Product would infringe any valid or enforceable claim of the '262 patent.

30. The Court should declare that Rubicon has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '262 patent.

COUNT IV
(Declaratory Judgment of Invalidity of U.S. Patent No. 8,987,262)

31. Rubicon incorporates by reference and re-alleges each of the foregoing Paragraphs of Rubicon's Answer and Affirmative Defenses to the Plaintiffs/Counterclaim Defendants Complaint for Patent Infringement and Paragraphs 1-18 of these Counterclaims as if fully set forth herein.

32. Upon information and belief, the claims of the '262 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

33. There is a real, substantial, and justiciable controversy between Rubicon and Plaintiffs/Counterclaim Defendants concerning whether the claims of the '262 patent are invalid and/or unenforceable for failure to comply with one or more of the requirements of Title 35 of the United States Code, including, without limitation, one or more §§ 101, 102, 103 and/or 112 *et seq.* and/or pursuant to common law and/or equitable doctrines.

34. The Court should declare that the claims of the '262 patent are invalid and/or unenforceable.

PRAYER FOR RELIEF

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

A. Declaring that the filing of Rubicon's ANDA No. 219574 has not and does not directly or indirectly infringe any valid claim of any of the Asserted Patents;

B. Declaring that the commercial manufacture, use, offer to sell, sale within the United States, and/or importation into the United States of Rubicon's Propranolol Hydrochloride Solution; Oral, 4.28 MG/ML described in ANDA No. 219574 does not, and would not, if marketed, directly or indirectly infringe any valid claim of the Asserted Patents;

C. Declaring that the claims of the Asserted Patents are invalid;

D. Ordering that judgment be entered in favor of Rubicon and that Plaintiffs/Counterclaim Defendants' Complaint be dismissed with prejudice;

E. Declaring this case exceptional and awarding Rubicon its reasonable attorney fees and costs of defending this action and prosecuting its counterclaims under 35 U.S.C. § 285; and

F. Awarding Rubicon such other and further relief as this Court deems just and proper.

Dated: September 4, 2024

Respectfully submitted,

/s/ Kaan Ekiner

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