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, v. RUBICON RESEARCH PRIVATE LIMITED, Defendant.	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Pierre Fabre Medicament SAS ("Pierre Fabre"); Université de Bordeaux ("Bordeaux"); Centre Hospitalier Universitaire de Bordeaux ("CHU"); and Pierre Fabre Pharmaceuticals, Inc. ("PFPI") (together, "Plaintiffs"), by and through their undersigned counsel, file this Complaint for patent infringement and declaratory judgment of patent infringement against Defendant Rubicon Research Private Limited ("Rubicon" or "Defendant"), and allege as follows:

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.

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.

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

PARTIES

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

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.

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.

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

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.

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.

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.

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).

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.

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

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.

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.

PIERRE FABRE'S HEMANGEOL PRODUCT

16. Pierre Fabre is 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.

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

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.

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

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."

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.

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.

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.”

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.

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.

27. The Asserted Patents are valid and enforceable.

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.

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

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.

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.

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

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.

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.

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.

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.

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.

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

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).

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

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.

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.

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.

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.

COUNT II – INFRINGEMENT OF THE '262 PATENT

45. Plaintiffs reallege and incorporate by reference 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.

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

PRAYER FOR RELIEF

59. **WHEREFORE**, Plaintiffs pray for judgment in their favor and against Rubicon for the following:

(a) A judgment that Rubicon has infringed the Asserted Patents under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 219574 and that making, using, offering to sell, selling, or importing into the United States Rubicon's ANDA Product will infringe one or more claims of the Asserted Patents;

(b) A finding that the Asserted Patents are valid and enforceable;

(c) An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 219574 shall be a date after the latest expiration date of the Asserted Patents;

(d) An order under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Rubicon and all persons acting or attempting to act in active concert or participation with Rubicon or on its behalf from engaging in the manufacture, use, offer to sell, sale, or importation into the United States of any drug product or use of a drug product that is covered by the Asserted Patents, including Rubicon's ANDA Product, during the term of the Asserted Patents;

(e) A judgment declaring that the commercial manufacture, use, sale, offer for sale, or importation of Rubicon's ANDA Product, or any other drug product that is covered by or the use of which is covered by, the Asserted Patents, prior to the expiration of the last to expire of the Asserted Patents, will infringe, induce the infringement of, and contribute to the infringement by others of, the Asserted Patents;

(f) A finding that this case is exceptional and award Plaintiffs their reasonable attorneys' fees in this action;

(g) Plaintiffs' costs in connection with this action; and

(h) An award of such other and further relief, at law or in equity, as the Court may deem just and proper.

Respectfully submitted,

Dated: July 12, 2024

/s/ John D. Simmons

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