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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BIOMARIN PHARMACEUTICAL INC. and MERCK & CIE, **Plaintiffs,** **v.** **AUROBINDO PHARMACEUTICALS LTD. and AUROBINDO PHARMA USA, INC.,** **Defendants.**	**Civil Action No.** _____ **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs BioMarin Pharmaceutical Inc. ("BioMarin") and Merck & Cie ("Merck") (collectively, "Plaintiffs"), by their undersigned attorneys, for their complaint against Aurobindo Pharmaceuticals Ltd. ("Aurobindo Ltd.) and Aurobindo Pharma USA, Inc. ("Aurobindo USA") (together, "Aurobindo"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Aurobindo's filing of a purported

Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially manufacture and market a generic version of the pharmaceutical drug product Kuvan® 100 mg. tablets prior to the expiration of U.S. Patent Nos. 7,566,462 ("the '462 patent"), 7,566,714 ("the '714 patent"), 7,612,073 ("the '073 patent"), 7,727,987 ("the '987 patent"), 8,003,126 ("the '126 patent"), 8,067,416 ("the '416 patent"), RE43,797 ("the '797 patent"), 8,318,745 ("the '745 patent"), and 9,433,624 ("the '624 patent") (collectively, the "patents-in-suit").

THE PARTIES

2. Plaintiff BioMarin is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 770 Lindaro Street, San Rafael, California 94901.

3. Plaintiff Merck is a Swiss corporation, having a principal place of business at Weisshausmatte, 6469 Altdorf, Switzerland.

4. Upon information and belief, Aurobindo Ltd. is a company organized under the laws of India having a principal place of business at Maitri Vihar, Plot #2, Ameerpet, Hyderabad – 500038, Telangana, India.

5. Upon information and belief, Aurobindo USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

6. Upon information and belief, Aurobindo USA is a wholly-owned subsidiary of Aurobindo Ltd.

7. Upon information and belief, Aurobindo Ltd., directly or through subsidiaries, including Aurobindo USA, is in the business of, among other things, manufacturing, marketing,

distributing, and selling generic versions of branded pharmaceutical products, which it distributes in New Jersey and throughout the United States.

JURISDICTION AND VENUE

8. Subject matter jurisdiction over this action is premised on 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Aurobindo USA by virtue of, *inter alia*, Aurobindo USA being a citizen of the State of New Jersey; having a presence in New Jersey; having conducted business in New Jersey; having availed itself of the rights and benefits of New Jersey law; purposefully availing itself of the privilege of conducting business in New Jersey; having previously consented to personal jurisdiction in this Court; and having engaged in systematic and continuous contacts with the State of New Jersey that render it essentially at home in the state. On information and belief, Aurobindo USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100921223. On information and belief, Aurobindo USA is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5003120.

10. This Court has personal jurisdiction over Aurobindo Ltd. because inter alia, it: (1) has purposefully availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, Aurobindo USA, a company with its principal place of business in New Jersey; and (2) maintains extensive and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Aurobindo USA.

11. This Court has personal jurisdiction over Aurobindo because, inter alia, it has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), including completing the act of infringement by delivery of notice of the ANDA submission to BioMarin and Merck. On information and belief, Aurobindo intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to BioMarin and Merck in New Jersey and in this Judicial District.

12. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

13. On July 28, 2009, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '462 patent, entitled "Stable Tablet Formulation," to BioMarin as assignee of the inventors Steven Jungles, Mark A. Henderson, Victoria Sluzky, and Robert Baffi. A copy of the '462 patent is attached hereto as Exhibit A.

14. BioMarin is the owner of all right, title, and interest in the '462 patent.

15. On July 28, 2009, the USPTO duly and lawfully issued the '714 patent, entitled "Methods and Compositions for the Treatment of Metabolic Disorders," to BioMarin as assignee of inventors Daniel I. Oppenheimer, Emil D. Kakkis, Frederic D. Price, Alejandro Dorenbaum, Rudolf Moser, Viola Groehn, Thomas Egger, and Fritz Blatter, including through assignment from Merck Eprova AG. Merck Eprova AG assigned all of its interest in the '714 patent to BioMarin. A copy of the '714 patent is attached hereto as Exhibit B.

16. BioMarin is the owner of all right, title, and interest in the '714 patent.

17. On November 3, 2009, the USPTO duly and lawfully issued the '073 patent, entitled "Methods of Administering Tetrahydrobiopterin, Associated Compositions, and Methods

of Measuring," to BioMarin as assignee of inventors Daniel I. Oppenheimer, Alejandro Dorenbaum, and Augustus Okhamafe. A copy of the '073 patent is attached hereto as Exhibit C.

18. BioMarin is the owner of all right, title, and interest in the '073 patent.

19. On June 1, 2010, the USPTO duly and lawfully issued the '987 patent, entitled "Crystalline Forms of (6R)-L-Erythro-Tetrahydrobiopterin Dihydrochloride," to Merck Eprova AG as assignee of inventors Rudolf Moser, Viola Groehn, Thomas Egger, and Fritz Blatter. Merck Eprova AG assigned all of its interest in the '987 patent to Merck & Cie KG, which then changed its name to Merck & Cie. A copy of the '987 patent is attached hereto as Exhibit D.

20. Merck is the owner of all right, title, and interest in the '987 patent. BioMarin is the exclusive licensee of the '987 patent.

21. On August 23, 2011, the USPTO duly and lawfully issued the '126 patent, entitled "Stable Tablet Formulation," to BioMarin as assignee of inventors Steven Jungles, Mark Henderson, Victoria Sluzky, and Robert Baffi. A copy of the '126 patent is attached hereto as Exhibit E.

22. BioMarin is the owner of all right, title, and interest in the '126 patent.

23. On November 29, 2011, the USPTO duly and lawfully issued the '416 patent, entitled "Methods and Compositions for the Treatment of Metabolic Disorders," to BioMarin as assignee of inventors Daniel I. Oppenheimer, Emil D. Kakkis, Frederic D. Price, Alejandro Dorenbaum, Rudolf Moser, Viola Groehn, Thomas Egger, and Fritz Blatter, including through assignment from Merck Eprova AG. Merck Eprova AG assigned all of its interest in the '416 patent to BioMarin. A copy of the '416 patent is attached hereto as Exhibit F.

24. BioMarin is the owner of all right, title, and interest in the '416 patent.

25. On November 6, 2012, the USPTO duly and lawfully issued the '797 patent, entitled "Methods of Administering Tetrahydrobiopterin," to BioMarin as assignee of inventors Daniel I. Oppenheimer, Alejandro Dorenbaum, and Augustus O. Okhamafe. The '797 patent is a reissue of U.S. Patent No. 7,947,681. A copy of the '797 patent is attached hereto as Exhibit G.

26. BioMarin is the owner of all right, title, and interest in the '797 patent.

27. On November 27, 2012, the USPTO duly and lawfully issued the '745 patent, entitled "Crystalline Forms of (6R)-L-Erythro-Tetrahydrobiopterin Dihydrochloride," to Merck as assignee of inventors Rudolf Moser, Viola Groehn, Thomas Egger, and Fritz Blatter, including through assignment from Merck Eprova AG and Merck & Cie KG. Merck Eprova AG assigned all of its interest in the '745 patent to Merck & Cie KG, which then changed its name to Merck & Cie. A copy of the '745 patent is attached hereto as Exhibit H.

28. Merck is the owner of all right, title, and interest in the '745 patent. BioMarin is the exclusive licensee of the '745 patent.

29. On September 6, 2016, the USPTO duly and lawfully issued the '624 patent, entitled "Methods and Compositions for the Treatment of Metabolic Disorders," to BioMarin as assignee of inventors Daniel I. Oppenheimer, Emil D. Kakkis, Frederic D. Price, Alejandro Dorenbaum, Rudolf Moser, Viola Groehn, Thomas Egger, and Fritz Blatter, including through assignment from Merck Eprova AG. Merck Eprova AG assigned all of its interest in the '624 patent to BioMarin. A copy of the '624 patent is attached hereto as Exhibit I.

30. BioMarin is the owner of all right, title, and interest in the '624 patent.

THE KUVAN® DRUG PRODUCT

31. BioMarin holds approved New Drug Application ("NDA") No. 022181 for oral tablets containing 100 mg of sapropterin dihydrochloride, sold under the trade name Kuvan®.

32. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Kuvan®.

ACTS GIVING RISE TO THIS ACTION

33. Upon information and belief, Aurobindo submitted to the FDA documentation purporting to constitute an ANDA pursuant to 21 U.S.C. § 355(j) (ANDA No. 216797), seeking approval to commercially manufacture, use, and market a generic version of the pharmaceutical drug product Kuvan® in the form of oral tablets containing 100 mg of sapropterin dihydrochloride ("Aurobindo's Generic Product"), prior to the expiration of the '462, '714, '073, '987, '126, '416, '797, '745, and '624 patents.

34. BioMarin and Merck received a letter from Aurobindo, dated March 8, 2022, with an attached memorandum (collectively, "Aurobindo's Notification"), stating that Aurobindo included certifications in its FDA submission, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Aurobindo's Generic Product (the "Paragraph IV certification"). Thus, Aurobindo is seeking approval of its proposed Generic Product prior to the expiration of the patents-in-suit.

35. Upon information and belief, if ANDA No. 216797 is approved, it is the intention of Aurobindo to commercially manufacture, use, and sell Aurobindo's Generic Product in the United States.

36. Upon information and belief, Aurobindo's purported ANDA relies upon the Kuvan® NDA and contains information purporting to show that Aurobindo's Generic Product (a) is bioequivalent to the patented Kuvan® product; (b) has the same active ingredient as the patented Kuvan® product; (c) has the same route of administration and strength as the patented

Kuvan® product; (d) has the same, or substantially the same, dosage form and proposed labeling as the patented Kuvan® product; and (e) has the same indication and usage as the patented Kuvan® product.

37. Plaintiffs are filing this complaint within the 45-day interval from receipt of Aurobindo's Notification, pursuant to 21 U.S.C. § 355(c)(3)(C). Plaintiffs reserve all rights to challenge the sufficiency of Aurobindo's purported ANDA and Paragraph IV certification.

COUNT ONE: INFRINGEMENT OF THE '462 PATENT

38. Plaintiffs repeat and reallege the allegations of paragraphs 1–37 as though fully set forth herein.

39. Submission of an ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of oral tablets containing 100 mg of sapropterin dihydrochloride prior to the expiration of the '462 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

40. Unless enjoined by this Court, upon FDA approval, Aurobindo will infringe the '462 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Aurobindo's Generic Product in the United States.

41. Unless enjoined by this Court, upon FDA approval, Aurobindo will induce infringement of the '462 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the '462 patent and knowledge that its acts are encouraging infringement.

42. Unless enjoined by this Court, upon FDA approval, Aurobindo will contributorily infringe the '462 patent under 35 U.S.C. § 271(c). Upon information and belief, Aurobindo has had and continues to have knowledge that Aurobindo's Generic Product is especially made or

especially adapted for a use that infringes the '462 patent and that there is no substantial non-infringing use for Aurobindo's Generic Product.

43. Aurobindo does not contest infringement of numerous claims of the '462 patent in Aurobindo's Notification. If Aurobindo had a factual or legal basis to contest infringement of any claim of the '462 patent, it was required by applicable regulations to state such basis in Aurobindo's Notification. *See* 21 CFR § 314.52 (requiring paragraph IV notice letter to include a detailed, claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug and as to which the applicant has submitted a paragraph IV certification).

44. Aurobindo's actions, including its reliance on the purported defenses and statements set forth in Aurobindo's Notification regarding the '462 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

45. Plaintiffs will be substantially and irreparably harmed if Aurobindo's infringement of the '462 patent is not enjoined.

46. Plaintiffs do not have an adequate remedy at law.

COUNT TWO: INFRINGEMENT OF THE '714 PATENT

47. Plaintiffs repeat and reallege the allegations of paragraphs 1–37 as though fully set forth herein.

48. Submission of an ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of oral tablets containing 100 mg of sapropterin dihydrochloride prior to the expiration of the '714 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

49. Unless enjoined by this Court, upon FDA approval, Aurobindo will induce infringement of the '714 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the '714 patent and knowledge that its acts are encouraging infringement.

50. Unless enjoined by this Court, upon FDA approval, Aurobindo will contributorily infringe the '714 patent under 35 U.S.C. § 271(c). Upon information and belief, Aurobindo has had and continues to have knowledge that Aurobindo's Generic Product is especially made or especially adapted for a use that infringes the '714 patent and that there is no substantial non-infringing use for Aurobindo's Generic Product.

51. Aurobindo does not contest infringement of numerous claims of the '714 patent in Aurobindo's Notification. If Aurobindo had a factual or legal basis to contest infringement of any claim of the '714 patent, it was required by applicable regulations to state such basis in Aurobindo's Notification. *See* 21 CFR § 314.52 (requiring paragraph IV notice letter to include a detailed, claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug and as to which the applicant has submitted a paragraph IV certification).

52. Aurobindo's actions, including its reliance on the purported defenses and statements set forth in Aurobindo's Notification regarding the '714 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

53. Plaintiffs will be substantially and irreparably harmed if Aurobindo's infringement of the '714 patent is not enjoined.

54. Plaintiffs do not have an adequate remedy at law.

COUNT THREE: INFRINGEMENT OF THE '073 PATENT

55. Plaintiffs repeat and reallege the allegations of paragraphs 1–37 as though fully set forth herein.

56. Submission of an ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of oral tablets containing 100 mg of sapropterin dihydrochloride prior to the expiration of the '073 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

57. Unless enjoined by this Court, upon FDA approval, Aurobindo will induce infringement of the '073 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the '073 patent and knowledge that its acts are encouraging infringement.

58. Unless enjoined by this Court, upon FDA approval, Aurobindo will contributorily infringe the '073 patent under 35 U.S.C. § 271(c). Upon information and belief, Aurobindo has had and continues to have knowledge that Aurobindo's Generic Product is especially made or especially adapted for a use that infringes the '073 patent and that there is no substantial non-infringing use for Aurobindo's Generic Product.

59. Aurobindo does not contest infringement of any claim of the '073 patent in Aurobindo's Notification. If Aurobindo had a factual or legal basis to contest infringement of any claim of the '073 patent, it was required by applicable regulations to state such basis in Aurobindo's Notification. *See* 21 CFR § 314.52 (requiring paragraph IV notice letter to include a detailed, claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug and as to which the applicant has submitted a paragraph IV certification).

60. Aurobindo's actions, including its reliance on the purported defenses and statements set forth in Aurobindo's Notification regarding the '073 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

61. Plaintiffs will be substantially and irreparably harmed if Aurobindo's infringement of the '073 patent is not enjoined.

62. Plaintiffs do not have an adequate remedy at law.

COUNT FOUR: INFRINGEMENT OF THE '987 PATENT

63. Plaintiffs repeat and reallege the allegations of paragraphs 1–37 as though fully set forth herein.

64. Submission of an ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of oral tablets containing 100 mg of sapropterin dihydrochloride prior to the expiration of the '987 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

65. Unless enjoined by this Court, upon FDA approval, Aurobindo will infringe the '987 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Aurobindo's Generic Product in the United States.

66. Unless enjoined by this Court, upon FDA approval, Aurobindo will induce infringement of the '987 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the '987 patent and knowledge that its acts are encouraging infringement.

67. Unless enjoined by this Court, upon FDA approval, Aurobindo will contributorily infringe the '987 patent under 35 U.S.C. § 271(c). Upon information and belief, Aurobindo has had and continues to have knowledge that Aurobindo's Generic Product is especially made or

especially adapted for a use that infringes the '987 patent and that there is no substantial non-infringing use for Aurobindo's Generic Product.

68. Aurobindo does not contest infringement of numerous claims of the '987 patent in Aurobindo's Notification. If Aurobindo had a factual or legal basis to contest infringement of any claim of the '987 patent, it was required by applicable regulations to state such basis in Aurobindo's Notification. *See* 21 CFR § 314.52 (requiring paragraph IV notice letter to include a detailed, claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug and as to which the applicant has submitted a paragraph IV certification).

69. Aurobindo's actions, including its reliance on the purported defenses and statements set forth in Aurobindo's Notification regarding the '987 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

70. Plaintiffs will be substantially and irreparably harmed if Aurobindo's infringement of the '987 patent is not enjoined.

71. Plaintiffs do not have an adequate remedy at law.

COUNT FIVE: INFRINGEMENT OF THE '126 PATENT

72. Plaintiffs repeat and reallege the allegations of paragraphs 1–37 as though fully set forth herein.

73. Submission of an ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of oral tablets containing 100 mg of sapropterin dihydrochloride prior to the expiration of the '126 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

74. Unless enjoined by this Court, upon FDA approval, Aurobindo will infringe the '126 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Aurobindo's Generic Product in the United States.

75. Unless enjoined by this Court, upon FDA approval, Aurobindo will induce infringement of the '126 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the '126 patent and knowledge that its acts are encouraging infringement.

76. Unless enjoined by this Court, upon FDA approval, Aurobindo will contributorily infringe the '126 patent under 35 U.S.C. § 271(c). Upon information and belief, Aurobindo has had and continues to have knowledge that Aurobindo's Generic Product is especially made or especially adapted for a use that infringes the '126 patent and that there is no substantial non-infringing use for Aurobindo's Generic Product.

77. Aurobindo does not contest infringement of numerous claims of the '126 patent in Aurobindo's Notification. If Aurobindo had a factual or legal basis to contest infringement of any claim of the '126 patent, it was required by applicable regulations to state such basis in Aurobindo's Notification. *See* 21 CFR § 314.52 (requiring paragraph IV notice letter to include a detailed, claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug and as to which the applicant has submitted a paragraph IV certification).

78. Aurobindo's actions, including its reliance on the purported defenses and statements set forth in Aurobindo's Notification regarding the '126 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

79. Plaintiffs will be substantially and irreparably harmed if Aurobindo's infringement of the '126 patent is not enjoined.

80. Plaintiffs do not have an adequate remedy at law.

COUNT SIX: INFRINGEMENT OF THE '416 PATENT

81. Plaintiffs repeat and reallege the allegations of paragraphs 1–37 as though fully set forth herein.

82. Submission of an ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of oral tablets containing 100 mg of sapropterin dihydrochloride prior to the expiration of the '416 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

83. Unless enjoined by this Court, upon FDA approval, Aurobindo will induce infringement of the '416 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the '416 patent and knowledge that its acts are encouraging infringement.

84. Unless enjoined by this Court, upon FDA approval, Aurobindo will contributorily infringe the '416 patent under 35 U.S.C. § 271(c). Upon information and belief, Aurobindo has had and continues to have knowledge that Aurobindo's Generic Product is especially made or especially adapted for a use that infringes the '416 patent and that there is no substantial non-infringing use for Aurobindo's Generic Product.

85. Aurobindo does not contest infringement of numerous claims of the '416 patent in Aurobindo's Notification. If Aurobindo had a factual or legal basis to contest infringement of any claim of the '416 patent, it was required by applicable regulations to state such basis in Aurobindo's Notification. *See* 21 CFR § 314.52 (requiring paragraph IV notice letter to include a detailed, claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any

patent that is listed in the Orange Book in conjunction with the reference listed drug and as to which the applicant has submitted a paragraph IV certification).

86. Aurobindo's actions, including its reliance on the purported defenses and statements set forth in Aurobindo's Notification regarding the '416 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

87. Plaintiffs will be substantially and irreparably harmed if Aurobindo's infringement of the '416 patent is not enjoined.

88. Plaintiffs do not have an adequate remedy at law.

COUNT SEVEN: INFRINGEMENT OF THE '797 PATENT

89. Plaintiffs repeat and reallege the allegations of paragraphs 1–37 as though fully set forth herein.

90. Submission of an ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of oral tablets containing 100 mg of sapropterin dihydrochloride prior to the expiration of the '797 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

91. Unless enjoined by this Court, upon FDA approval, Aurobindo will induce infringement of the '797 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the '797 patent and knowledge that its acts are encouraging infringement.

92. Unless enjoined by this Court, upon FDA approval, Aurobindo will contributorily infringe the '797 patent under 35 U.S.C. § 271(c). Upon information and belief, Aurobindo has had and continues to have knowledge that Aurobindo's Generic Product is especially made or

especially adapted for a use that infringes the '797 patent and that there is no substantial non-infringing use for Aurobindo's Generic Product.

93. Aurobindo does not contest infringement of numerous claims of the '797 patent in Aurobindo's Notification. If Aurobindo had a factual or legal basis to contest infringement of any claim of the '797 patent, it was required by applicable regulations to state such basis in Aurobindo's Notification. *See* 21 CFR § 314.52 (requiring paragraph IV notice letter to include a detailed, claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug and as to which the applicant has submitted a paragraph IV certification).

94. Aurobindo's actions, including its reliance on the purported defenses and statements set forth in Aurobindo's Notification regarding the '797 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

95. Plaintiffs will be substantially and irreparably harmed if Aurobindo's infringement of the '797 patent is not enjoined.

96. Plaintiffs do not have an adequate remedy at law.

COUNT EIGHT: INFRINGEMENT OF THE '745 PATENT

97. Plaintiffs repeat and reallege the allegations of paragraphs 1–37 as though fully set forth herein.

98. Submission of an ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of oral tablets containing 100 mg of sapropterin dihydrochloride prior to the expiration of the '745 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

99. Unless enjoined by this Court, upon FDA approval, Aurobindo will infringe the '745 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Aurobindo's Generic Product in the United States.

100. Unless enjoined by this Court, upon FDA approval, Aurobindo will induce infringement of the '745 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the '745 patent and knowledge that its acts are encouraging infringement.

101. Unless enjoined by this Court, upon FDA approval, Aurobindo will contributorily infringe the '745 patent under 35 U.S.C. § 271(c). Upon information and belief, Aurobindo has had and continues to have knowledge that Aurobindo's Generic Product is especially made or especially adapted for a use that infringes the '745 patent and that there is no substantial non-infringing use for Aurobindo's Generic Product.

102. Aurobindo does not contest infringement of numerous claims of the '745 patent in Aurobindo's Notification. If Aurobindo had a factual or legal basis to contest infringement of any claim of the '745 patent, it was required by applicable regulations to state such basis in Aurobindo's Notification. *See* 21 CFR § 314.52 (requiring paragraph IV notice letter to include a detailed, claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug and as to which the applicant has submitted a paragraph IV certification).

103. Aurobindo's actions, including its reliance on the purported defenses and statements set forth in Aurobindo's Notification regarding the '745 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

104. Plaintiffs will be substantially and irreparably harmed if Aurobindo's infringement of the '745 patent is not enjoined.

105. Plaintiffs do not have an adequate remedy at law.

COUNT NINE: INFRINGEMENT OF THE '624 PATENT

106. Plaintiffs repeat and reallege the allegations of paragraphs 1–37 as though fully set forth herein.

107. Submission of an ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of oral tablets containing 100 mg of sapropterin dihydrochloride prior to the expiration of the '624 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

108. Unless enjoined by this Court, upon FDA approval, Aurobindo will infringe the '624 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Aurobindo's Generic Product in the United States.

109. Unless enjoined by this Court, upon FDA approval, Aurobindo will induce infringement of the '624 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the '624 patent and knowledge that its acts are encouraging infringement.

110. Unless enjoined by this Court, upon FDA approval, Aurobindo will contributorily infringe the '624 patent under 35 U.S.C. § 271(c). Upon information and belief, Aurobindo has had and continues to have knowledge that Aurobindo's Generic Product is especially made or especially adapted for a use that infringes the '624 patent and that there is no substantial non-infringing use for Aurobindo's Generic Product.

111. Aurobindo does not contest infringement of any claim of the '624 patent in Aurobindo's Notification. If Aurobindo had a factual or legal basis to contest infringement of

any claim of the '624 patent, it was required by applicable regulations to state such basis in Aurobindo's Notification. *See* 21 CFR § 314.52 (requiring paragraph IV notice letter to include a detailed, claim-by-claim analysis of its bases for claiming non-infringement or invalidity of any patent that is listed in the Orange Book in conjunction with the reference listed drug and as to which the applicant has submitted a paragraph IV certification).

112. Aurobindo's actions, including its reliance on the purported defenses and statements set forth in Aurobindo's Notification regarding the '624 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

113. Plaintiffs will be substantially and irreparably harmed if Aurobindo's infringement of the '624 patent is not enjoined.

Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs BioMarin and Merck pray for a Judgment in their favor and against Aurobindo, and respectfully request the following relief:

A. A Judgment that Aurobindo has infringed the '462, '714, '073, '987, '126, '416, '797, '745, and '624 patents;

B. A Judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Aurobindo, its officers, agents, servants, employees, and those persons in active concert or participation with any of them, from commercially manufacturing, using, offering to sell, or selling Aurobindo's Generic Product within the United States, or importing Aurobindo's Generic Product into the United States, prior to the expiration of the patents-in-suit;

C. A Judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 216797 under§ 505(j) of the Federal Food, Drug and Cosmetic

Act (21 U.S.C. § 355(j)) shall not be any earlier than the expiration date of the patents-in-suit, including any extensions;

D. If Aurobindo commercially manufactures, uses, offers to sell, or sells Aurobindo's Generic Product within the United States, or imports Aurobindo's Generic Product into the United States, prior to the expiration of the patents-in-suit, including any extensions, a Judgment awarding Plaintiffs monetary relief together with interest;

E. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

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

Dated: April 22, 2022

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or any pending arbitration or administrative proceeding.

Dated: April 22, 2022

By: s/ Charles M. Lizza

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