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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BIOMARIN PHARMACEUTICAL INC. and MERCK & CIE, **Plaintiffs,** **v.** **PAR PHARMACEUTICAL, INC.,** **Defendant.**	**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 Par Pharmaceutical, Inc. ("Par"), 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 Par'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® 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"), and 8,318,745 ("the '745 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, Par is a corporation incorporated under the laws of the State of Delaware, having a place of business and corporate headquarters at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

5. Upon information and belief, Par 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.

6. Upon information and belief, Par is registered to do business in the State of New Jersey under Business ID Number 0100071541, and is registered as a manufacturer and wholesaler of drugs in the State of New Jersey under Registration Number 5004032.

JURISDICTION AND VENUE

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

8. This Court has personal jurisdiction over Par by virtue of, *inter alia*, Par having a presence in New Jersey; Par having conducted business in New Jersey; Par having availed itself

of the rights and benefits of New Jersey law; Par purposefully availing itself of the privilege of conducting business in New Jersey; Par having previously consented to personal jurisdiction in this Court; and Par having engaged in systematic and continuous contacts with the State of New Jersey that render it essentially at home in the state.

9. Upon information and belief, i) Par is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, which, either directly or through its subsidiaries, agents and/or alter-egos, Par manufactures, distributes, markets and sells throughout the United States and in this Judicial District; ii) Par purposefully has conducted and continues to conduct business, directly, and/or through its subsidiaries, agents and/or alter-egos, in this Judicial District; iii) this Judicial District is a likely destination of Par's product that is the subject of this lawsuit; and iv) Par maintains a place of business and corporate headquarters in this Judicial District.

10. Par has availed itself of the benefits and protections of the laws of New Jersey and its court system such that it should reasonably anticipate being haled into court in this District. Par has stipulated and/or consented to personal jurisdiction before this Court in numerous other patent cases, both by filing suit in this District and by filing counterclaims in this District, including, but not limited to, in the following cases: *Par Pharm., Inc. et al. v. Breckenridge Pharm., Inc.*, Civil Action No. 13-4000 (RMB)(JS); *Par Pharm., Inc. v. Endo Pharm., Inc.*, Civil Action No. 05-1758 (JAP)(MCA); *Pharm. Res., Inc. and Par Pharm., Inc. v. Roxane Labs., Inc.*, Civil Action No. 03-3357 (DRD)(MCA); *Jazz Pharm., Inc. v Par Pharm., Inc.*, Civil Action No. 15-173 (ES)(JAD); *Jazz Pharm., Inc. et al. v Par Pharm., Inc.*, Civil Action No. 14-6150 (ES)(JAD); *Jazz Pharm., Inc. v Par Pharm., Inc.*, Civil Action No. 14-5139 (ES)(JAD); *Jazz Pharm., Inc. v Par Pharm., Inc.*, Civil Action No. 13-7884 (ES)(MAH); *Purdue Pharm. Prods.*

L.P. et al. v. Par Pharm., Inc., Civil Action No. 12-6738 (JLL)(MAH); *Depomed, Inc. v. Impax Labs., Inc. et al.*, Civil Action No. 12-2154 (JAP)(TJB); *Schering-Plough HealthCare Prods., Inc. et al. v. Par Pharm., Inc.*, Civil Action No. 10-4837 (PGS)(LHG); *Medeva Pharma Suisse A.G. et al. v. Par Pharm., Inc. et al.*, Civil Action No. 10-4008 (MAS)(TJB); *Sanofi-Aventis U.S. LLC et al. v. Mustafa Nevzat Ilac Sanayii A.S. et al.*, Civil Action No. 08-263 (JAP)(DEA); *Sanofi-Aventis U.S. LLC et al. v. Mustafa Nevzat Ilac Sanayii A.S. et al.*, Civil Action No. 07-3143 (JAP)(JJH); *Novartis Corp. et al v. Par Pharm. Cos., Inc. et al.*, Civil Action No. 06-6283 (HAA)(ES); *Novartis Corp. et al v. Par Pharm. Cos., Inc. et al.*, Civil Action No. 06-4788 (HAA)(ES); *Ortho-McNeil Pharm., Inc. v. Kali Labs., Inc. et al.*, Civil Action No. 06-3533 (DMC)(MF); *CIMA Labs Inc. v. Par Pharm. Cos., Inc. et al.,* Civil Action No. 06-1970 (CCC)(MF); *Schwarz Pharma, Inc. et al. v. Par Pharm. Cos., Inc. et al.*, Civil Action No. 06-1999 (DRD)(ES); *Apotex Inc. et al. v. Pharm. Res. Inc. et al.*, Civil Action No. 06-1153 (JLL)(MF); and *Abbott Labs. et al. v. Par Pharm., Inc.*, Civil Action No. 04-325 (JAP)(MCA).

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

THE PATENTS-IN-SUIT

12. 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.

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

14. 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.

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

16. 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.

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

18. 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.

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

20. 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.

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

22. 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.

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

24. 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.

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

26. 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.

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

THE KUVAN® DRUG PRODUCT

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

29. 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

30. Upon information and belief, Par submitted to the FDA documentation purporting to constitute an ANDA pursuant to 21 U.S.C. § 355(j) (ANDA No. 207200), 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 ("Par's Generic Product"), prior to the expiration of the '462, '714, '073, '987, '126, '416, '797, and '745 patents.

31. BioMarin and Merck received a letter from Par, dated January 22, 2015, with an attached memorandum (collectively, "Par's Notification"), stating that Par 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 Par's Generic Product (the "Paragraph IV certification"). Thus, Par is seeking approval of its proposed Generic Product prior to the expiration of the patents-in-suit.

32. Upon information and belief, if ANDA No. 207200 is approved, it is the intention of Par to commercially manufacture, use, and sell Par's Generic Product in the United States.

33. Upon information and belief, Par's purported ANDA relies upon the Kuvan® NDA and contains information purporting to show that Par'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.

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

COUNT ONE: INFRINGEMENT OF THE '462 PATENT

35. Plaintiffs repeat and reallege the allegations of paragraphs 1–34 as though fully set forth herein.

36. 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).

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

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

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

40. Par does not contest infringement of any claim of the '462 patent in Par's Notification. If Par 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 Par'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).

41. Par's actions, including its reliance on the purported defenses and statements set forth in Par'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.

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

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

COUNT TWO: INFRINGEMENT OF THE '714 PATENT

44. Plaintiffs repeat and reallege the allegations of paragraphs 1–43 as though fully set forth herein.

45. 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).

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

47. Unless enjoined by this Court, upon FDA approval, Par will contributorily infringe the '714 patent under 35 U.S.C. § 271(c). Upon information and belief, Par has had and continues to have knowledge that Par'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 Par's Generic Product.

48. Par does not contest infringement of any claim of the '714 patent in Par's Notification. If Par 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 Par'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).

49. Par's actions, including its reliance on the purported defenses and statements set forth in Par'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.

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

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

COUNT THREE: INFRINGEMENT OF THE '073 PATENT

52. Plaintiffs repeat and reallege the allegations of paragraphs 1–51 as though fully set forth herein.

53. 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).

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

55. Unless enjoined by this Court, upon FDA approval, Par will contributorily infringe the '073 patent under 35 U.S.C. § 271(c). Upon information and belief, Par has had and continues to have knowledge that Par'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 Par's Generic Product.

56. Par does not contest infringement of any claim of the '073 patent in Par's Notification. If Par 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 Par'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).

57. Par's actions, including its reliance on the purported defenses and statements set forth in Par'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.

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

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

COUNT FOUR: INFRINGEMENT OF THE '987 PATENT

60. Plaintiffs repeat and reallege the allegations of paragraphs 1–59 as though fully set forth herein.

61. 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).

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

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

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

65. Par does not contest infringement of claims 9-20 of the '987 patent in Par's Notification. If Par had a factual or legal basis to contest infringement of claims 9-20 of the '987

patent, it was required by applicable regulations to state such basis in Par'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).

66. Par's actions, including its reliance on the purported defenses and statements set forth in Par'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.

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

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

COUNT FIVE: INFRINGEMENT OF THE '126 PATENT

69. Plaintiffs repeat and reallege the allegations of paragraphs 1–68 as though fully set forth herein.

70. 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).

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

72. Unless enjoined by this Court, upon FDA approval, Par will induce infringement of the '126 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval,

Par will intentionally encourage acts of direct infringement with knowledge of the '126 patent and knowledge that its acts are encouraging infringement.

73. Unless enjoined by this Court, upon FDA approval, Par will contributorily infringe the '126 patent under 35 U.S.C. § 271(c). Upon information and belief, Par has had and continues to have knowledge that Par'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 Par's Generic Product.

74. Par does not contest infringement of any claim of the '126 patent in Par's Notification. If Par 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 Par'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).

75. Par's actions, including its reliance on the purported defenses and statements set forth in Par'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.

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

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

COUNT SIX: INFRINGEMENT OF THE '416 PATENT

78. Plaintiffs repeat and reallege the allegations of paragraphs 1–77 as though fully set forth herein.

79. 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).

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

81. Unless enjoined by this Court, upon FDA approval, Par will contributorily infringe the '416 patent under 35 U.S.C. § 271(c). Upon information and belief, Par has had and continues to have knowledge that Par'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 Par's Generic Product.

82. Par does not contest infringement of any claim of the '416 patent in Par's Notification. If Par 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 Par'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).

83. Par's actions, including its reliance on the purported defenses and statements set forth in Par'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.

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

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

COUNT SEVEN: INFRINGEMENT OF THE '797 PATENT

86. Plaintiffs repeat and reallege the allegations of paragraphs 1–85 as though fully set forth herein.

87. 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).

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

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

90. Par does not contest infringement of any claim of the '797 patent in Par's Notification. If Par 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 Par'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).

91. Par's actions, including its reliance on the purported defenses and statements set forth in Par'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.

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

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

COUNT EIGHT: INFRINGEMENT OF THE '745 PATENT

94. Plaintiffs repeat and reallege the allegations of paragraphs 1–93 as though fully set forth herein.

95. 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).

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

97. Unless enjoined by this Court, upon FDA approval, Par will induce infringement of the '745 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval,

Par will intentionally encourage acts of direct infringement with knowledge of the '745 patent and knowledge that its acts are encouraging infringement.

98. Unless enjoined by this Court, upon FDA approval, Par will contributorily infringe the '745 patent under 35 U.S.C. § 271(c). Upon information and belief, Par has had and continues to have knowledge that Par'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 Par's Generic Product.

99. Par does not contest infringement of any claim of the '745 patent in Par's Notification. If Par 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 Par'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).

100. Par's actions, including its reliance on the purported defenses and statements set forth in Par'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.

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

102. 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 Par, and respectfully request the following relief:

A. A Judgment be entered that Par has infringed the ’462, ’714, ’073, ’987, ’126, ’416, ’797, and ’745 patents;

B. A Judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Par, 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 Par’s Generic Product within the United States, or importing Par’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. 207200 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 Par commercially manufactures, uses, offers to sell, or sells Par’s Generic Product within the United States, or imports Par’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: March 6, 2015

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 & 40.1, I hereby certify that the matter captioned *BioMarin Pharmaceutical Inc. and Merck & Cie v. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd.*, Civil Action No. 14-7203 (MAS)(TJB) is related to the matter in controversy because said matter involves the same Plaintiffs and seven of the eight patents at issue in the present case.

Dated: March 6, 2015

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