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*Attorneys for Plaintiff  
BioMarin Pharmaceutical Inc.*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**BIOMARIN PHARMACEUTICAL INC.,**

**Plaintiff,**

**v.**

**DR. REDDY'S LABORATORIES, INC.  
and DR. REDDY'S LABORATORIES,  
LTD.,**

**Defendants.**

**Civil Action No. \_\_\_\_\_**

**COMPLAINT FOR  
PATENT INFRINGEMENT**

**(Filed Electronically)**

Plaintiff BioMarin Pharmaceutical Inc. ("BioMarin"), by its undersigned attorneys, for its complaint against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL"), alleges 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 DRL'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<sup>®</sup> (100 mg powder) prior to the expiration of U.S. Patent Nos. 7,566,714 ("the '714 patent"), 7,612,073 ("the '073 patent"), 8,067,416 ("the '416 patent"), RE43,797 ("the '797 patent"), 9,216,178 ("the '178 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 Lindero Street, San Rafael, California 94901.

3. Upon information and belief, Dr. Reddy's Laboratories, Inc. is a corporation incorporated under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540. Upon information and belief, Dr. Reddy's Laboratories, Inc. is in the business of, among other things, marketing and selling generic versions of branded pharmaceutical products, which it distributes in New Jersey and throughout the United States.

4. Upon information and belief, Dr. Reddy's Laboratories, Ltd. is a company organized under the laws of India, having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, 500 034, India. Upon information and belief, Dr. Reddy's Laboratories, Ltd. is in the business of making and selling generic pharmaceutical products,

which it distributes in New Jersey and throughout the United States through at least Dr. Reddy's Laboratories, Inc.

5. Upon information and belief, Dr. Reddy's Laboratories, Inc. is a subsidiary of Dr. Reddy's Laboratories, Ltd.

6. Upon information and belief, Dr. Reddy's Laboratories, Inc. is the exclusive agent in North America for Dr. Reddy's Laboratories, Ltd.

7. Upon information and belief, Dr. Reddy's Laboratories, Inc. is registered to do business in the State of New Jersey under Business ID Number 0100518911, and is registered as a manufacturer and wholesaler of drugs in the State of New Jersey under Registration Number 5002312.

#### **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 DRL by virtue of, *inter alia*, DRL having a presence (including Dr. Reddy's Laboratories, Inc.'s principal place of business) in New Jersey, DRL having conducted business in New Jersey, DRL having availed itself of the rights and benefits of New Jersey law, DRL purposefully availing itself of the privilege of conducting business in New Jersey, DRL having previously consented to personal jurisdiction in this Court, and DRL having engaged in systematic and continuous contacts with the State of New Jersey that render it at home in the State.

10. Upon information and belief, (i) DRL 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, that DRL manufactures, distributes, markets and sells throughout the United States and in this

Judicial District; (ii) DRL 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 DRL's product that is the subject of this lawsuit; and (iv) Dr. Reddy's Laboratories, Inc. maintains its principal place of business and its administrative offices in this Judicial District.

11. BioMarin (and another plaintiff) previously sued DRL in this Judicial District for infringement of the patents-in-suit (plus four additional patents) with respect to DRL's proposed generic version of Kuvan® in the 100 mg tablet dosage form in a case that has since been dismissed (*BioMarin Pharmaceutical Inc., et al. v. Dr. Reddy's Labs., Inc., et al.*, Civil Action No. 14-7203 (MAS)(TJB)). DRL acknowledged in that action that jurisdiction is proper in this District.

12. DRL 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. In addition to the previous case filed by BioMarin described above, DRL has stipulated and/or consented to personal jurisdiction before this Court in numerous other patent cases, including, but not limited to, in the following cases: *Janssen Pharm. N.V. v. Dr. Reddy's Labs., Ltd.*, Civil Action No. 03-6185 (D.N.J.) (JWB); *Teva Pharm. Indus. v. Dr. Reddy's Labs., Ltd.*, Civil Action No. 07-2894 (D.N.J.) (GEB) (JJH); *Hoffmann La Roche Inc. v. Dr. Reddy's Labs., Ltd.*, Civil Action No. 07-4516 (D.N.J.) (SRC) (CCC); *Astrazeneca UK Ltd. v. Dr. Reddy's Labs., Ltd.*, Civil Action No. 08-3237 (D.N.J.) (MLC) (TJB); *Albany Molecular Research, Inc. v. Dr. Reddy's Labs., Ltd.*, Civil Action No. 09-4638 (D.N.J.) (JAG) (MCA); *The Meds. Co. v. Dr. Reddy's Labs., Ltd.*, Civil Action No. 11-2456 (D.N.J.) (PGS) (DEA); *Helsinn Healthcare S.A. v. Dr. Reddy's Labs., Ltd.*, Civil Action No. 12-2867 (D.N.J.) (MLC) (DEA); *Astrazeneca AB v.*

*Dr. Reddy's Labs., Ltd.*, Civil Action No. 13-91 (D.N.J.) (JAP) (TJB); and *Horizon Pharma, Inc. v. Dr. Reddy's Labs. Inc.*, Civil Action No. 16-9035 (D.N.J.) (MLC)(DEA).

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

### **THE PATENTS-IN-SUIT**

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 and Merck Eprova AG as assignees of inventors Daniel I. Oppenheimer, Emil D. Kakkis, Frederic D. Price, Alejandro Dorenbaum, Rudolf Moser, Viola Groehn, Thomas Egger, and Fritz Blatter. Merck Eprova AG subsequently assigned all of its interest in the '714 patent to BioMarin. A copy of the '714 patent is attached hereto as Exhibit A.

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 B.

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

18. 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 and Merck Eprova AG as assignees of inventors Daniel I. Oppenheimer, Emil D. Kakkis, Frederic D. Price, Alejandro Dorenbaum, Rudolf Moser, Viola Groehn, Thomas Egger, and Fritz Blatter. Merck Eprova AG subsequently assigned all of its interest in the '416 patent to BioMarin. A copy of the '416 patent is attached hereto as Exhibit C.

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

20. 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 D.

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

22. On December 22, 2015, the USPTO duly and lawfully issued the '178 patent, entitled "Dry Blend Formulation of Tetrahydrobiopterin," to BioMarin as assignee of inventors Tianwei Chou and Augustus Okhamafe. A copy of the '178 patent is attached hereto as Exhibit E.

23. BioMarin is the owner of all right, title, and interest in the '178 patent.

24. 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. A copy of the '624 patent is attached hereto as Exhibit F.

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

**THE KUVAN® POWDER DRUG PRODUCT**

26. BioMarin holds approved New Drug Application ("NDA") No. 205065 for packets (or sachets) of powder containing 100 mg of sapropterin dihydrochloride, sold under the trade name Kuvan®.

27. 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® in the 100 mg powder dosage form.

**DRL's FDA SUBMISSION AND ACTS GIVING RISE TO THIS ACTION**

28. Upon information and belief, DRL submitted to the FDA documentation purporting to constitute an ANDA pursuant to 21 U.S.C. § 355(j) (ANDA No. 209452), seeking approval to commercially manufacture, use, and market a generic version of the pharmaceutical drug product Kuvan® in the 100 mg powder dosage form (“DRL’s Generic Product”), prior to the expiration of the patents-in-suit.

29. BioMarin received a letter from DRL, dated December 23, 2016, with an attached memorandum (collectively, “DRL’s Notification”), stating that DRL included certifications in its ANDA, 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 DRL’s Generic Product (the “Paragraph IV certification”). Thus, DRL is seeking approval of its proposed Generic Product prior to the expiration of the patents-in-suit.

30. Upon information and belief, if ANDA No. 209452 is approved, it is the intention of DRL to commercially manufacture, use, and sell DRL’s Generic Product in the United States.

31. DRL’s purported ANDA relies upon the Kuvan® powder NDA and contains information purporting to show that DRL’s Generic Product (a) is bioequivalent to the patented Kuvan® 100 mg powder product; (b) has the same active ingredient as the patented Kuvan® 100 mg powder product; (c) has the same route of administration and strength as the patented Kuvan® 100 mg powder product; (d) has the same, or substantially the same, dosage form and proposed labeling as the patented Kuvan® 100 mg powder product; and (e) has the same indication and usage as the patented Kuvan® 100 mg powder product.

32. BioMarin is filing this complaint within 45 days of receiving DRL’s Notification, pursuant to 21 U.S.C. § 355(c)(3)(C). BioMarin reserves all rights to challenge the sufficiency of DRL’s purported ANDA and Paragraph IV certification.

**COUNT ONE: INFRINGEMENT OF THE '714 PATENT**

33. BioMarin repeats and realleges the allegations of paragraphs 1-32 as though fully set forth herein.

34. Submission of an ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of DRL's Generic Product 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).

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

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

37. DRL does not contest infringement of claims 1-5, 11, 18-21, 28, and 43-46 of the '714 patent in DRL's Notification. If DRL had a factual or legal basis to contest infringement of claims 1-5, 11, 18-21, 28, and 43-46 of the '714 patent, it was required by applicable regulations to state such basis in DRL'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).



38. DRL's actions, including its reliance on the purported defenses and statements set forth in DRL'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 BioMarin to recovery of its attorneys' fees and such other relief as this Court deems proper.

39. BioMarin will be substantially and irreparably harmed if DRL's infringement of the '714 patent is not enjoined.

40. BioMarin does not have an adequate remedy at law.

**COUNT TWO: INFRINGEMENT OF THE '073 PATENT**

41. BioMarin repeats and realleges the allegations of paragraphs 1-40 as though fully set forth herein.

42. Submission of an ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of DRL's Generic Product 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).

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

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

45. DRL's actions, including its reliance on the purported defenses and statements set forth in DRL'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 BioMarin to recovery of its attorneys' fees and such other relief as this Court deems proper.

46. BioMarin will be substantially and irreparably harmed if DRL's infringement of the '073 patent is not enjoined.

47. BioMarin does not have an adequate remedy at law.

**COUNT THREE: INFRINGEMENT OF THE '416 PATENT**

48. BioMarin repeats and realleges the allegations of paragraphs 1-47 as though fully set forth herein.

49. Submission of an ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of DRL's Generic Product 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).

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

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

52. DRL does not contest infringement of claims 1, 3-7, and 14-18 of the '416 patent in DRL's Notification. If DRL had a factual or legal basis to contest infringement of claims 1, 3-7, and 14-18 of the '416 patent, it was required by applicable regulations to state such basis in DRL'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).

53. DRL's actions, including its reliance on the purported defenses and statements set forth in DRL'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 BioMarin to recovery of its attorneys' fees and such other relief as this Court deems proper.

54. BioMarin will be substantially and irreparably harmed if DRL's infringement of the '416 patent is not enjoined.

55. BioMarin does not have an adequate remedy at law.

**COUNT FOUR: INFRINGEMENT OF THE '797 PATENT**

56. BioMarin repeats and realleges the allegations of paragraphs 1-55 as though fully set forth herein.

57. Submission of an ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of DRL's Generic Product 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).

58. Unless enjoined by this Court, upon FDA approval, DRL will induce infringement of the '797 patent under 35 U.S.C. § 271(b). Upon information and belief, upon

FDA approval, DRL will intentionally encourage acts of direct infringement with knowledge of the '797 patent and knowledge that its acts are encouraging infringement.

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

60. DRL's actions, including its reliance on the purported defenses and statements set forth in DRL'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 BioMarin to recovery of its attorneys' fees and such other relief as this Court deems proper.

61. BioMarin will be substantially and irreparably harmed if DRL's infringement of the '797 patent is not enjoined.

62. BioMarin does not have an adequate remedy at law.

**COUNT FIVE: INFRINGEMENT OF THE '178 PATENT**

63. BioMarin repeats and realleges the allegations of paragraphs 1-62 as though fully set forth herein.

64. Submission of an ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of DRL's Generic Product prior to the expiration of the '178 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, DRL will infringe the '178 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling DRL's Generic Product in the United States.

66. Unless enjoined by this Court, upon FDA approval, DRL will induce infringement of the '178 patent under 35 U.S.C. § 271(b). Upon information and belief, upon FDA approval, DRL will intentionally encourage acts of direct infringement with knowledge of the '178 patent and knowledge that its acts are encouraging infringement.

67. Unless enjoined by this Court, upon FDA approval, DRL will contributorily infringe the '178 patent under 35 U.S.C. § 271(c). Upon information and belief, DRL has had and continues to have knowledge that DRL's Generic Product is especially made or especially adapted for a use that infringes the '178 patent and that there is no substantial non-infringing use for DRL's Generic Product.

68. DRL's actions, including its reliance on the purported defenses and statements set forth in DRL's Notification regarding the '178 patent, warrant a finding that this case is an exceptional case pursuant to 35 U.S.C. § 285, and entitle BioMarin to recovery of its attorneys' fees and such other relief as this Court deems proper.

69. BioMarin will be substantially and irreparably harmed if DRL's infringement of the '178 patent is not enjoined.

70. BioMarin does not have an adequate remedy at law.

**COUNT SIX: INFRINGEMENT OF THE '624 PATENT**

71. BioMarin repeats and realleges the allegations of paragraphs 1-70 as though fully set forth herein.

72. Submission of an ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of DRL's Generic Product 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).

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

74. Unless enjoined by this Court, upon FDA approval, DRL will contributorily infringe the '624 patent under 35 U.S.C. § 271(c). Upon information and belief, DRL has had and continues to have knowledge that DRL'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 DRL's Generic Product.

75. DRL does not contest infringement of claims 1-6 and 10-12 of the '624 patent in DRL's Notification. If DRL had a factual or legal basis to contest infringement of claims 1-6 and 10-12 of the '624 patent, it was required by applicable regulations to state such basis in DRL'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).

76. DRL's actions, including its reliance on the purported defenses and statements set forth in DRL'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 BioMarin to recovery of its attorneys' fees and such other relief as this Court deems proper.

77. BioMarin will be substantially and irreparably harmed if DRL's infringement of the '624 patent is not enjoined.

78. BioMarin does not have an adequate remedy at law.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff BioMarin prays for a Judgment in its favor and against DRL, and respectfully requests the following relief:

- A. A Judgment be entered that DRL has infringed the patents-in-suit;
- B. A Judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining DRL, 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 DRL's Generic Product within the United States, or importing DRL'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. 209452 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 DRL commercially manufactures, uses, offers to sell, or sells DRL's Generic Product within the United States, or imports DRL's Generic Product into the United States, prior to the expiration of the patents-in-suit, including any extensions, a Judgment awarding BioMarin 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: February 6, 2017

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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 consolidated matters captioned as *BioMarin Pharmaceutical Inc., et al. v. Par Pharmaceutical, Inc.*, Civil Action No. 15-1706 (MAS)(TJB) and *BioMarin Pharmaceutical Inc., et al. v. Par Pharmaceutical, Inc.*, Civil Action No. 16-1015 (MAS)(TJB) are related to the matter in controversy because those matters involve the same plaintiff and five of the six patents at issue in the present case (Case No. 15-1706 also involves two additional patents).

I further 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 of any pending arbitration or administrative proceeding.

Dated: February 6, 2017

Of Counsel:

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