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

| | |
|---|---|
| **BIOMARIN PHARMACEUTICAL INC.,**<br><br>**Plaintiff,**<br><br>**v.**<br><br>**PAR PHARMACEUTICAL, INC.,**<br><br>**Defendant.** | **Civil Action No. _____**<br><br>**COMPLAINT FOR PATENT INFRINGEMENT**<br><br>**(Filed Electronically)** |

Plaintiff BioMarin Pharmaceutical Inc. ("BioMarin"), by its undersigned attorneys, for its complaint against Par Pharmaceutical, Inc. ("Par"), 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 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® (100 mg packets) 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"), and RE43,797 ("the '797 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. Par is a corporation incorporated under the laws of the State of Delaware, having a place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677. Upon information and belief, Par's principal place of business and administrative offices are located at that New Jersey address.

4. Par is in the business of manufacturing, marketing, and selling, *inter alia*, generic pharmaceutical products. Upon information and belief, Par distributes these generic pharmaceutical products in New Jersey and throughout the United States.

5. 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

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

7. This Court has personal jurisdiction over Par by virtue of, *inter alia*, Par having a presence (including a place of business) 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.

8. 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 its principal place of business and its administrative offices in this Judicial District.

9. A related case is pending in this Judicial District where BioMarin and another plaintiff have sued Par for infringement of the patents-in-suit (plus four additional patents) with respect to Par's proposed generic version of Kuvan® in the 100 mg tablet dosage form (*BioMarin Pharmaceutical Inc. and Merck & Cie v. Par Pharm., Inc.*, Civil Action No. 15-1706 (MAS)(TJB)). Par has acknowledged in that action that jurisdiction is proper in this 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. In addition to the related case described above, 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 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 '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 A.

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

14. 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.

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

16. 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 C.

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

18. 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.

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

## THE KUVAN® POWDER DRUG PRODUCT

20. 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®.

21. 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 packet dosage form.

## ACTS GIVING RISE TO THIS ACTION

22. 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. 207207), seeking approval to commercially manufacture, use, and market a generic version of the pharmaceutical drug product Kuvan® in the 100 mg packet dosage form ("Par's Generic Product"), prior to the expiration of the patents-in-suit.

23. BioMarin received a letter from Par, dated January 14, 2016, with an attached memorandum (collectively, "Par's Notification"), stating that Par 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 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.

24. Upon information and belief, if ANDA No. 207207 is approved, it is the intention of Par to commercially manufacture, use, and sell Par's Generic Product in the United States.

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

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

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

27. BioMarin repeats and realleges the allegations of paragraphs 1-26 as though fully set forth herein.

28. Submission of an ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Par'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).

29. 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.

30. 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.

31. 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).

32. 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 BioMarin to recovery of its attorneys' fees and such other relief as this Court deems proper.

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

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

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

35. BioMarin repeats and realleges 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 manufacture, use, sale, offer for sale, or importation of Par'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).

37. 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.

38. 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.

39. 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).

40. 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 BioMarin to recovery of its attorneys' fees and such other relief as this Court deems proper.

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

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

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

43. BioMarin repeats and realleges the allegations of paragraphs 1-42 as though fully set forth herein.

44. Submission of an ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Par'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).

45. 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.

46. 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.

47. 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).

48. 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 BioMarin to recovery of its attorneys' fees and such other relief as this Court deems proper.

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

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

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

51. BioMarin repeats and realleges the allegations of paragraphs 1-50 as though fully set forth herein.

52. Submission of an ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Par'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).

53. 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.

54. 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.

55. 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).

56. 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 BioMarin to recovery of its attorneys' fees and such other relief as this Court deems proper.

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

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

**PRAYER FOR RELIEF**

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

A. A Judgment be entered that Par has infringed the patents-in-suit;

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. 207207 under the Federal Food, Drug and Cosmetic Act 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 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 22, 2016

By: s/ Charles M. Lizza

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*BioMarin Pharmaceutical Inc.*

**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., et al. v. Par Pharmaceutical, Inc.*, Civil Action No. 15-1706 (MAS)(TJB) is related to the matter in controversy because said matter involves the same plaintiff (plus one additional plaintiff), the same defendant, and all four patents at issue (plus four additional patents) in the present case.

Dated: February 22, 2016

By: s/ Charles M. Lizza

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