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Luitpold Pharmaceuticals, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

LUITPOLD PHARMACEUTICALS, INC.,

Plaintiff,

v.

AMNEAL PHARMACEUTICALS, LLC, AMNEAL HOLDINGS, LLC, AMNEAL PHARMACEUTICALS HOLDING COMPANY, LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, and AMNEAL PHARMACEUTICALS CO. INDIA PRIVATE LIMITED,

Defendants;

RECORDATI IRELAND LIMITED, an Irish company,

Defendant Patent Owner.

Civil Action No. _____

Hon. _____, U.S.D.J.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Luitpold Pharmaceuticals, Inc. ("Luitpold"), by its undersigned attorneys, brings this Complaint and action for patent infringement against Amneal Pharmaceuticals, LLC ("Amneal Pharma"), Amneal Holdings, LLC ("Amneal Holdings"), Amneal Pharmaceuticals Holding Company, LLC ("Amneal Pharmaceutical Holding"), Amneal Pharmaceuticals of New York, LLC ("Amneal NY"), and Amneal Pharmaceuticals Co. India Private Limited ("Amneal India") (collectively "the Amneal Defendants"), and hereby alleges as follows:

THE PARTIES

1. Plaintiff Luitpold Pharmaceuticals, Inc. is a corporation organized under the laws of the State of New York and has its principal place of business at One Luitpold Drive, Shirley, New York, 11967.

2. On information and belief, Amneal Pharma is a limited liability company organized under the laws of the State of Delaware, having a principal place of business at 440 U.S. Highway 22 East, Suite 104, Bridgewater, New Jersey, 08807, and is the parent corporation of Amneal NY and Amneal India. Amneal Pharma is in the business of, among other things, manufacturing and marketing generic copies of branded pharmaceutical products throughout the United States and this District.

3. On information and belief, Amneal Holdings is a corporation organized under the laws of the State of Delaware, and is the parent corporation of Amneal Pharma. Amneal Holdings is in the business of, among other things, manufacturing and marketing generic copies of branded pharmaceutical products throughout the United States including this District.

4. On information and belief, Amneal Pharmaceutical Holding is a corporation organized under the laws of the State of Delaware, and is the parent corporation of Amneal Pharma. Amneal Pharmaceutical Holding is in the business of, among other things,

manufacturing and marketing generic copies of branded pharmaceutical products throughout the United States including this District.

5. On information and belief, Amneal NY is a corporation organized under the laws of the State of Delaware, having a principal place of business at 85 Adams Avenue, Hauppage, New York, 11788, and is a subsidiary of Amneal Pharma. Amneal NY is in the business of, among other things, manufacturing and marketing generic copies of branded pharmaceutical products throughout the United States including this District.

6. On information and belief, Amneal India is an Indian corporation having a principal place of business at 882/1-871, Rajoda Village, Near Hotel Kankavati, Bavla Taluka, Ahmedabad-38220, Gujurat, India, and is a subsidiary of Amneal Pharma. Amneal India is in the business of, among other things, manufacturing and marketing generic copies of branded pharmaceutical products throughout the United States including this District.

7. On information and belief, Amneal Pharma, Amneal Holdings, Amneal Pharmaceutical Holding, Amneal NY and Amneal India hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling and distributing generic pharmaceutical products.

8. Defendant patent owner Recordati Ireland Limited ("Recordati") is a company organized under the laws of the Republic of Ireland and has its principal place of business at Raheens East, Ringaskiddy, Cork County, Ireland.

NATURE OF THE ACTION

9. This is an action for infringement of United States Patent Number 6,333,044 ("the '044 patent"), arising under the United States patent laws, Title 35, United States Code, §§ 100 *et seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Amneal Pharma's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug

and Cosmetic Act ("the Act"), 21 U.S.C. §355(j) seeking U.S. Food and Drug Administration ("FDA") approval to market a generic pharmaceutical product.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over Amneal Pharma because Amneal Pharma resides in this District and it has purposely availed itself of the benefits and protections of the laws of New Jersey such that it should reasonably anticipate being haled into Court here. In addition, on information and belief, Amneal Pharma has had continuous and systematic contacts with this judicial district, including: (1) being registered to do business in New Jersey, (2) having its headquarters in New Jersey, (3) having branches of business in New Jersey, (4) conducting business in New Jersey, (5) directly, or indirectly, manufacturing, marketing, selling, and distributing generic drugs throughout the United States and in this judicial district, (6) purposely conducting and continuing to conduct business in this judicial district, and (7) the fact that this judicial district is a likely destination of Amneal Pharma's generic products. In addition, Amneal Pharma has a past practice of consenting to personal jurisdiction in this judicial district for other patent litigation matters. Thus, Amneal Pharma is subject to general jurisdiction in New Jersey.

12. This Court has personal jurisdiction over Amneal Holdings because Amneal Holdings has purposely availed itself of the benefits and protections of the laws of New Jersey such that it should reasonably anticipate being haled into Court here. In addition, on information and belief, Amneal Holdings has had continuous and systematic contacts with this judicial district, including: (1) engaging in the business of manufacturing, marketing, importing, selling and distributing pharmaceutical drug products, including generic drug products within this

judicial district, (2) directly or indirectly, in partnership and agency with its subsidiary Amneal Pharma, conducting business within the judicial district, and (3) directly or indirectly, and in partnership and agency with its subsidiary Amneal Pharma, manufacturing, marketing, selling and distributing generic drugs throughout the United States and in this judicial district. Thus, Amneal Holdings is subject to general jurisdiction in New Jersey.

13. This Court has personal jurisdiction over Amneal Pharmaceutical Holding because Amneal Pharmaceutical Holding has purposely availed itself of the benefits and protections of the laws of New Jersey such that it should reasonably anticipate being haled into Court here. In addition, on information and belief, Amneal Pharmaceutical Holding has had continuous and systematic contacts with this judicial district, including: (1) engaging in the business of manufacturing, marketing, importing, selling and distributing pharmaceutical drug products, including generic drug products within this judicial district, (2) directly or indirectly, in partnership and agency with its subsidiary Amneal Pharma, conducting business within the judicial district, and (3) directly or indirectly, and in partnership and agency with its subsidiary Amneal Pharma, manufacturing, marketing, selling and distributing generic drugs throughout the United States and in this judicial district. Thus, Amneal Pharmaceutical Holding is subject to general jurisdiction in New Jersey.

14. This Court has personal jurisdiction over Amneal NY because Amneal NY has purposely availed itself of the benefits and protections of the laws of New Jersey such that it should reasonably anticipate being haled into Court here. In addition, on information and belief, Amneal NY has had continuous and systematic contacts with this judicial district, including: (1) engaging in the business of manufacturing, marketing, importing, selling and distributing pharmaceutical drug products, including generic drug products within this judicial district, (2) directly or indirectly, in partnership and agency with its parent corporation Amneal Pharma,

conducting business within the judicial district, and (3) directly or indirectly, and in partnership and agency with its parent corporation Amneal Pharma, manufacturing, marketing, selling and distributing generic drugs throughout the United States and in this judicial district. Thus, Amneal NY is subject to general jurisdiction in New Jersey.

15. This Court has personal jurisdiction over Amneal India because Amneal India has purposely availed itself of the benefits and protections of the laws of New Jersey such that it should reasonably anticipate being haled into Court here. In addition, on information and belief, Amneal India has had continuous and systematic contacts with this judicial district, including: (1) engaging in the business of manufacturing, marketing, importing, selling and distributing pharmaceutical drug products, including generic drug products within this judicial district, (2) directly or indirectly, in partnership and agency with its parent corporation Amneal Pharma, conducting business within the judicial district, and (3) directly or indirectly, and in partnership and agency with its parent corporation Amneal Pharma, manufacturing, marketing, selling and distributing generic drugs throughout the United States and in this judicial district. Thus, Amneal India is subject to general jurisdiction in New Jersey.

16. Recordati is named as a party to this litigation as a defendant patent owner. Recordati is the lawful assignee of all right, title and interest in the '044 patent and, as detailed below, has granted an exclusive license to practice the '044 patent. The exclusive license and all rights thereunder are held by Luitpold. As a result, Luitpold has the right and standing to enforce the '044 patent and to bring this action. Further, Recordati has an interest in the outcome of this litigation, is subject to personal jurisdiction in this Court, and is a proper party to this action, as a plaintiff, defendant, or involuntary plaintiff, whichever designation is deemed appropriate by the Court.

17. Recordati has acknowledged and does not dispute that Luitpold holds an exclusive license to the '044 patent and has the exclusive right to enforce the '044 patent against the Amneal Defendants in the United States and to bring the present lawsuit.

18. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 28 U.S.C. § 1400(b).

THE '044 PATENT

19. Luitpold holds an approved New Drug Application ("NDA"), No. 22-382, by which the FDA granted approval under Section 505(a) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(a), for Ketorolac Tromethamine Nasal Spray, 15.75 mg/spray. The Ketorolac Tromethamine Nasal Spray described in NDA No. 22-382 is marketed and sold by Luitpold in the United States under the trademark SPRIX®.

20. Recordati is the owner of the '044 patent.

21. The '044 patent was duly and legally issued on December 25, 2001. A true and correct copy of the '044 patent is attached hereto as Exhibit A.

22. The '044 patent was assigned by the inventors to Recordati, S.A. Chemical and Pharmaceutical Company, which in 2007 assigned it to Recordati. Thus, Recordati is the lawful assignee of the '044 patent.

23. On or about November 23, 2000, Roxro Pharma, Inc. or its predecessor-in-interest (hereinafter "Roxro") entered into an exclusive license agreement with Recordati or its predecessor-in-interest to the '044 patent, wherein it received an exclusive license to U.S. patent rights relating to the "intranasal formulations of the compound known as Ketorolac as described in Patent Application US 08/383707, filed February 1, 1995," which became the '044 patent. The rights under that exclusive license include, but are not limited to, the right to pursue any infringement claims against infringers of the '044 patent.

24. In December 2010, Luitpold acquired Roxro. Roxro has assigned its rights in and to its exclusive license to the '044 patent to Luitpold such that Luitpold is now the exclusive licensee of the '044 patent.

25. Pursuant to 21 U.S.C. § 355(b)(1) and applicable FDA regulations, the '044 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to SPRIX®.

COUNT ONE

INFRINGEMENT OF THE '044 PATENT
(AMNEAL PHARMA)

26. Luitpold realleges and incorporates by reference paragraphs 1 through 25 as if fully set forth herein.

27. Amneal Pharma submitted an ANDA (No. 204113) to the FDA under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic ketorolac tromethamine 15.75 mg/nasal spray (hereinafter referred to as "Amneal's ANDA product").

28. Amneal Pharma submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Amneal's ANDA product prior to expiration of the '044 patent.

29. The relevant statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) requires that a notice of the paragraph IV certification ("Notice Letter") "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA's rules and regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

30. On or about June 28, 2012, Amneal Pharma sent to Luitpold a Notice Letter, purporting to comply with the provisions of 21 U.S.C. § 355(j)(2)(B)(iv)(II) and the FDA regulations relating thereto.

31. Amneal Pharma made a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, Amneal's ANDA product will not directly or indirectly infringe claims 4, 8, 10, 35 and 50 of the '044 patent, either literally or under the doctrine of equivalents. Amneal Pharma did not allege in the Amneal Notice Letter that the Amneal Product will not infringe claims 1-3, 5-7, 9, 11-34, 36-49 and 51 of the '044 Patent.

32. Amneal Pharma also alleged in the Amneal Notice Letter that claims 1-3, 5-7, 9, 11-34, 36-49 and 51 of the '044 Patent are invalid for obviousness under 35 U.S.C. § 103. Amneal Pharma did not allege in the Amneal Notice Letter that claims 4, 8, 10, 35 and 50 of the '044 Patent are invalid.

33. The opinions set forth in the Amneal Notice Letter that the '044 patent is not infringed and is invalid due to obviousness and other potential, unnamed theories, are devoid of an objective, good faith basis in either the facts or law. Amneal Pharma's Paragraph IV certification is a wholly unjustified infringement of the '044 patent.

34. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the Amneal's ANDA product before expiration of the '044 patent, Amneal Pharma has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, unless enjoined by this Court, Amneal Pharma, upon FDA approval of Amneal's ANDA, will infringe the '044 patent by making, using, offering to sell, selling and/or importing Amneal's ANDA product in the United States.

35. Amneal Pharma's method of manufacturing Amneal's ANDA product will infringe the '044 Patent, either literally or under the doctrine of equivalents, violating 35 U.S.C. §

271(a), (b) and (c).

36. Amneal Pharma's manufacturing, marketing, offering for sale, sale, and/or importation for sale of Amneal's ANDA product will induce the infringement of, and/or contributorily infringe, one or more claims of the '044 patent that teach a method in connection with ketorolac tromethamine nasal spray. This will occur at Amneal Pharma's active behest, and with its specific intent, knowledge and encouragement. On information and belief, Amneal Pharma will actively induce, encourage, aid, abet, and/or contribute to, infringement of one or more claims of the '044 patent with the knowledge that it is in contravention of Luitpold's rights under the '044 patent.

37. On information and belief, when Amneal Pharma filed its ANDA, it was aware of the '044 patent and that the filing of its ANDA with the request for its approval prior to the expiration date of the '044 patent was an act of infringement.

38. Amneal Pharma has violated its duty of care to avoid the known patent rights of the '044 patent.

39. There is a justiciable controversy between the parties hereto as to infringement and validity of certain claims of the '044 patent.

40. Luitpold is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval of the aforementioned ANDA relating to Amneal's ANDA product be a date which is not earlier than December 25, 2018, the expiration of the '044 patent, or any later date of exclusivity to which Luitpold is or becomes entitled. Further, Luitpold is entitled to an award of damages for any commercial manufacture, use, offer for sale, sale, and/or importation of Amneal's ANDA product, and any act committed by Amneal with respect to the subject matter claimed in the '044 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

41. On information and belief, prior to filing ANDA No. 22-382, the Amneal Defendants were aware of the existence of the '044 patent, and, were aware that the filing of ANDA No. 22-382, including a certification pursuant to 21 U.S.C. § 355(j)(A)(vii)(IV) with respect to the '044 patent, infringed that patent.

42. This is an exceptional case, and Luitpold is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

43. Luitpold will be substantially and irreparably damaged and harmed if Amneal Pharma is not enjoined from infringing or actively inducing or contributing to infringement of the '044 patent. Luitpold does not have an adequate remedy at law.

COUNT TWO

INFRINGEMENT OF THE '044 PATENT (AMNEAL HOLDINGS)

44. Luitpold realleges and incorporates by reference paragraphs 1 through 43 as if fully set forth herein.

45. On information and belief, Amneal Holdings initiates, directs and controls the activities of its subsidiary company, Amneal Pharma, with regard to ANDA No. 22-382, and Amneal's ANDA product.

46. On information and belief, Amneal Holdings, through Amneal Pharma as its agent, initiated, directed and controlled preparation and filing of ANDA No. 22-382 with the FDA.

47. On information and belief, Amneal Holdings has infringed the '044 patent under 35 U.S.C. § 271(e)(2)(A) by initiating, directing and controlling the preparation and filing of ANDA No. 22-382.

48. On information and belief, in the event that the FDA approves ANDA No. 22-382, Amneal Holdings stands to benefit directly from such approval by being able to commercially manufacture and distribute Amneal's ANDA product.

49. Amneal's ANDA product for which Amneal Holdings, through Amneal Pharma as its agent, seeks approval under ANDA No. 22-382, will infringe one or more claims of the '044 patent under 35 U.S.C. § 271(a).

50. The commercial manufacture, use, offer for sale, sale, and/or importation into the United States, by Amneal Holdings of Amneal's ANDA product directly or indirectly infringe one or more claims of the '044 patent under 35 U.S.C. § 271(a), (b) or (c).

51. The manufacture of Amneal's ANDA product by Amneal Holdings will infringe the '044 Patent, either literally or under the doctrine of equivalents, violating 35 U.S.C. § 271(a), (b) and (c).

52. Luitpold is entitled to full relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 22-382 be a date that is not earlier than the later of December 25, 2018, the expiration of the '044 patent, or the expiration of any other exclusivity to which Luitpold is or becomes entitled.

53. On information and belief, prior to filing ANDA No. 22-382, the Amneal Defendants were aware of the existence of the '044 patent, and, were aware that the filing of ANDA No. 22-382, including a certification pursuant to 21 U.S.C. § 355(j)(A)(vii)(IV) with respect to the '044 patent, infringed that patent.

54. This is an exceptional case, and Luitpold is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

55. Luitpold will be substantially and irreparably damaged and harmed if Amneal Holdings is not enjoined from infringing or actively inducing or contributing to infringement of the '044 patent. Luitpold does not have an adequate remedy at law.

COUNT THREE

INFRINGEMENT OF THE '044 PATENT
(AMNEAL PHARMACEUTICAL HOLDING)

56. Luitpold realleges and incorporates by reference paragraphs 1 through 55 as if fully set forth herein.

57. On information and belief, Amneal Pharmaceutical Holding initiates, directs and controls the activities of its subsidiary company, Amneal Pharma, with regard to ANDA No. 22-382, and Amneal's ANDA product.

58. On information and belief, Amneal Pharmaceutical Holding, through Amneal Pharma as its agent, initiated, directed and controlled preparation and filing of ANDA No. 22-382 with the FDA.

59. On information and belief, Amneal Pharmaceutical Holding has infringed the '044 patent under 35 U.S.C. § 271(e)(2)(A) by initiating, directing and controlling the preparation and filing of ANDA No. 22-382.

60. On information and belief, in the event that the FDA approves ANDA No. 22-382, Amneal Pharmaceutical Holding stands to benefit directly from such approval by being able to commercially manufacture and distribute Amneal's ANDA product.

61. Amneal's ANDA product for which Amneal Pharmaceutical Holding, through Amneal Pharma as its agent, seeks approval under ANDA No. 22-382, will infringe one or more claims of the '044 patent under 35 U.S.C. § 271(a).

62. The commercial manufacture, use, offer for sale, sale, and/or importation into the United States, by Amneal Pharmaceutical Holding of Amneal's ANDA product directly or indirectly infringe one or more claims of the '044 patent under 35 U.S.C. § 271(a), (b) or (c).

63. The manufacture of Amneal's ANDA product by Amneal Pharmaceutical Holding will infringe the '044 Patent, either literally or under the doctrine of equivalents, violating 35 U.S.C. § 271(a), (b) and (c).

64. Luitpold is entitled to full relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 22-382 be a date that is not earlier than the later of December 25, 2018, the expiration of the '044 patent, or the expiration of any other exclusivity to which Luitpold is or becomes entitled.

65. On information and belief, prior to filing ANDA No. 22-382, the Amneal Defendants were aware of the existence of the '044 patent, and, were aware that the filing of ANDA No. 22-382, including a certification pursuant to 21 U.S.C. § 355(j)(A)(vii)(IV) with respect to the '044 patent, infringed that patent.

66. This is an exceptional case, and Luitpold is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

67. Luitpold will be substantially and irreparably damaged and harmed if Amneal Pharmaceutical Holding is not enjoined from infringing or actively inducing or contributing to infringement of the '044 patent. Luitpold does not have an adequate remedy at law.

COUNT FOUR

INFRINGEMENT OF THE '044 PATENT (AMNEAL NY)

68. Luitpold realleges and incorporates by reference paragraphs 1 through 67 as if fully set forth herein.

69. On information and belief, Amneal Pharma initiates, directs and controls the activities of its subsidiary company, Amneal NY, with regard to ANDA No. 22-382, and Amneal's ANDA product.

70. On information and belief, Amneal NY, under the control of Amneal Pharma, was involved with the preparation and filing of ANDA No. 22-382 with the FDA.

71. On information and belief, Amneal NY has infringed the '044 patent under 35 U.S.C. § 271(e)(2)(A) by its involvement with the preparation and filing of ANDA No. 22-382.

72. On information and belief, in the event that the FDA approves ANDA No. 22-382, Amneal NY stands to benefit directly from such approval by being able to commercially manufacture and distribute Amneal's ANDA product.

73. The commercial manufacture, use, offer for sale, sale, and/or importation into the United States, of Amneal's ANDA product will directly or indirectly infringe one or more claims of the '044 patent under 35 U.S.C. § 271(a), (b) or (c).

74. The manufacture of Amneal's ANDA product by Amneal NY will infringe the '044 Patent, either literally or under the doctrine of equivalents, violating 35 U.S.C. § 271(a), (b) and (c).

75. Luitpold is entitled to full relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 22-382 be a date that is not earlier than the later of December 25, 2018, the expiration of the '044 patent, or the expiration of any other exclusivity to which Luitpold is or becomes entitled.

76. On information and belief, prior to filing ANDA No. 22-382, the Amneal Defendants were aware of the existence of the '044 patent, and, were aware that the filing of ANDA No. 22-382, including a certification pursuant to 21 U.S.C. § 355(j)(A)(vii)(IV) with respect to the '044 patent, infringed that patent.

77. This is an exceptional case, and Luitpold is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

78. Luitpold will be substantially and irreparably damaged and harmed if Amneal NY is not enjoined from infringing or actively inducing or contributing to infringement of the '044 patent. Luitpold does not have an adequate remedy at law.

COUNT FIVE

INFRINGEMENT OF THE '044 PATENT (AMNEAL INDIA)

79. Luitpold realleges and incorporates by reference paragraphs 1 through 78 as if fully set forth herein.

80. On information and belief, Amneal Pharma initiates, directs and controls the activities of its subsidiary company, Amneal India, with regard to ANDA No. 22-382, and Amneal's ANDA product.

81. On information and belief, Amneal India, under the control of Amneal Pharma, was involved with the preparation and filing of ANDA No. 22-382 with the FDA.

82. On information and belief, Amneal India has infringed the '044 patent under 35 U.S.C. § 271(e)(2)(A) by its involvement with the preparation and filing of ANDA No. 22-382.

83. On information and belief, in the event that the FDA approves ANDA No. 22-382, Amneal India stands to benefit directly from such approval by being able to commercially manufacture and distribute Amneal's ANDA product.

84. The commercial manufacture, use, offer for sale, sale, and/or importation into the United States, of Amneal's ANDA product will directly or indirectly infringe one or more claims of the '044 patent under 35 U.S.C. § 271(a), (b) or (c).

85. The manufacture of Amneal's ANDA product by Amneal India will infringe the '044 Patent, either literally or under the doctrine of equivalents, violating 35 U.S.C. § 271(a), (b) and (c).

86. Luitpold is entitled to full relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 22-382 be a date that is not earlier than the later of December 25, 2018, the expiration of the '044 patent, or the expiration of any other exclusivity to which Luitpold is or becomes entitled.

87. On information and belief, prior to filing ANDA No. 22-382, the Amneal Defendants were aware of the existence of the '044 patent, and, were aware that the filing of ANDA No. 22-382, including a certification pursuant to 21 U.S.C. § 355(j)(A)(vii)(IV) with respect to the '044 patent, infringed that patent.

88. This is an exceptional case, and Luitpold is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

89. Luitpold will be substantially and irreparably damaged and harmed if Amneal India is not enjoined from infringing or actively inducing or contributing to infringement of the '044 patent. Luitpold does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Luitpold respectfully requests the following relief:

A. A judgment declaring that the Amneal Defendants have infringed one or more claims of the '044 patent through the submission of ANDA No. 204113 to the FDA, and that the Amneal Defendants' manufacturing, using, selling, offering for sale, and/or importation of Amneal's ANDA product will infringe one or more claims of the '044 patent;

B. A judgment declaring that the Amneal Defendants' manufacture, use, sale, offer for sale, and/or importation into the United States of Amneal's ANDA product would constitute infringement of one or more claims of the '044 patent;

C. A judgment declaring that the Amneal Defendants' manufacture, use, sale, offer for sale, and/or importation into the United States of Amneal's ANDA product would induce and/or contribute to infringement of one or more claims of the '044 patent, pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

D. A judgment ordering, pursuant to 35 U.S.C. § 271(e)(4), that the effective date of any FDA approval of Amneal ANDA No. 204113 be a date which is not earlier than the expiration of the '044 patent, or any later expiration of exclusivity to which Luitpold is or becomes entitled;

E. Entry of a preliminary and permanent injunction enjoining the Amneal Defendants' and their officers, agents, servants, employees, parent corporations, subsidiaries, and affiliates, and those persons in privity or in active concert or participation with any of them, from making, using, selling, offering to sell and/or importing into the United States, Amneal's ANDA product, for which approval is sought in ANDA No. 204113, or any ketorolac tromethamine nasal spray product that infringes and/or induces and/or contributes to the infringement of the '044 patent, until expiration of that patent, or any later expiration of exclusivity to which Luitpold is or becomes entitled;

F. If the Amneal Defendants engage in the commercial manufacture, use, importation of Amneal's ANDA product or any ketorolac tromethamine nasal spray product that infringes and/or induces and/or contributes to the infringement of the '044 patent, prior to the expiration of the '044 patent or any later expiration of exclusivity to which Luitpold is or becomes entitled, a judgment awarding damages to Luitpold resulting from such infringement, together with interest;

G. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

H. An award of costs and expenses in this action; and

I. Such further and other relief as this Court determines to be just and proper.

Dated: August 10, 2012

Respectfully submitted,

RIKER DANZIG SCHERER HYLAND & PERRETTI LLP

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CERTIFICATION OF NON-ARBITRABILITY

Pursuant to Local Civil Rule 201.1(d)(1), the undersigned attorney for Plaintiff, Luitpold Pharmaceuticals, Inc., certifies that this action is not eligible for arbitration under Local Civil Rule 201.1 because the relief sought in the Complaint primarily consists of a demand for preliminary and permanent injunctive relief, as well as damages believed to be in excess of $150,000.00, exclusive of interest, costs, and any claim for punitive damages.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned attorney for Plaintiff, Luitpold Pharmaceuticals, Inc., certifies that, to the best of his knowledge, the matter in controversy concerning the products and patent at issue herein is not the subject of another action pending in any court or in any arbitration or administrative proceeding.

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& PERRETTI LLP
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Luitpold Pharmaceuticals, Inc.

By s/ *Robert J. Schoenberg*
ROBERT J. SCHOENBERG

Dated: August 10, 2012