IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CMP DEVELOPMENT, LLC,	)	
	)	C.A. No.
Plaintiff,	)	
	)	
v.	)	
	)	
AMNEAL PHARMACEUTICALS LLC,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff CMP Development, LLC ("CMP"), by and through its attorneys, for its Complaint against Defendant Amneal Pharmaceuticals LLC ("Amneal"), alleges as follows:

THE NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent Nos. 9,757,394 ("the '394 patent"), 10,493,083 ("the '083 patent"), 10,624,906 ("the '906 patent"), 10,660,907 ("the '907 patent"), and 10,888,570 ("the '570 patent") (collectively, the "Patents-in-Suit") under the patent laws of the United States, Title 35, United States Code § 100 *et. seq.,* including 35 U.S.C. §§ 271 and 281.

2. This action relates to the submission by Amneal of Abbreviated New Drug Application No. 215572 to the U.S. Food and Drug Administration ("FDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) (hereafter, "the Amneal ANDA").

3. The Amneal ANDA seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of a generic form of CMP's CaroSpir® product before expiration of the Patents-in-Suit (hereafter, the "Amneal ANDA Product").

4. CMP seeks all available relief under the patent laws of the United States, 35 U.S.C. § 100, et seq., and other applicable laws for Amneal's infringement of the Patents-in-Suit.

PARTIES

5. CMP is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 8026 U.S. 264A, Farmville, NC 27828.

6. Amneal is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807.

7. Amneal is in the business of, among other things, developing, manufacturing, and selling generic forms of branded pharmaceutical products in the United States market, including in the State of Delaware.

8. Amneal intends to commercially manufacture, market, offer for sale, and sell its Amneal ANDA Product in the State of Delaware, in the event of FDA approval of the Amneal ANDA.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States of America, 35 U.S.C. § 100, *et seq*. and from submission of the Amneal ANDA.

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

11. This Court has personal jurisdiction over Amneal because of, among other things, Amneal's persistent and continuous contacts with Delaware. Amneal has purposefully availed itself of the benefits and protections of Delaware's laws repeatedly, such that it should reasonably anticipate being haled into court here.

12. Amneal is a limited liability company formed under the laws of the State of Delaware and is registered to do business in Delaware.

13. Amneal regularly and continuously transacts business in Delaware, including by selling pharmaceutical products in Delaware.

14. On information and belief, Amneal derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

15. This judicial district is a likely destination of the product that is the subject of the Amneal ANDA.

16. The Amneal ANDA relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Amneal's intent to market and sell the Amneal ANDA Product in this judicial district.

17. Amneal has taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of the Amneal ANDA Product—which will be purposefully directed at the District of Delaware.

18. Amneal intends to direct sales of its generic drugs in this judicial district once Amneal receives the requested FDA approval to market the Amneal ANDA Product, as it holds active pharmacy wholesale licenses in the state of Delaware and active controlled substances distributor/manufacturer licenses in the state of Delaware.

19. Amneal will engage in marketing of its Amneal ANDA Product in Delaware upon approval of the Amneal ANDA.

20. Amneal has, on several occasions, consented to personal jurisdiction of this Court in ANDA-related matters.

21. Amneal has, on several occasions, consented to Venue before this Court in ANDA-related matters.

22. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

CMP'S CAROSPIR® PRODUCT

23. CMP is the holder of New Drug Application ("NDA") No. 209478 for CaroSpir®, an oral suspension available in a dosage strength of 25 mg/5 mL (hereafter, "CaroSpir®").

24. The FDA approved CaroSpir® on August 4, 2017.

25. CaroSpir® includes spironolactone, which is an antagonist of aldosterone.

26. CaroSpir® is indicated for the treatment of heart failure, hypertension, and edema caused by cirrhosis.

27. CaroSpir® was the first, and remains the only, FDA-approved ready-to-use oral suspension with spironolactone.

28. CaroSpir® is an option for patients with dysphagia who have difficulty swallowing, or who cannot swallow tablets, and thus need a liquid form of spironolactone.

29. CaroSpir® eliminated the complexities and inconsistencies of compounding tablets containing spironolactone, which could result in unstable or inconsistent dosing for the patient.

PATENTS-IN-SUIT

30. Pursuant to 21 U.S.C. § 355, the '394, '083, '906, '907 and '570 patents are listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book") in connection with the CaroSpir® product.

31. The '394 patent, entitled "Spironolactone Aqueous Formulations," was duly and lawfully issued by the USPTO on September 12, 2017. A true and correct copy of the '394 patent is attached hereto as Exhibit A.

32. The ’083 patent, entitled “Spironolactone Aqueous Compositions,” was duly and lawfully issued by the USPTO on December 3, 2019. A true and correct copy of the ’083 patent is attached hereto as Exhibit B.

33. The ’906 patent, entitled “Spironolactone Aqueous Compositions,” was duly and lawfully issued by the USPTO on April 21, 2020. A true and correct copy of the ’906 patent is attached hereto as Exhibit C.

34. The ’907 patent, entitled “Spironolactone Aqueous Compositions,” was duly and lawfully issued by the USPTO on May 26, 2020. A true and correct copy of the ’907 patent is attached hereto as Exhibit D.

35. The ’570 patent, entitled “Spironolactone Aqueous Compositions,” was duly and lawfully issued by the USPTO on January 12, 2021. A true and correct copy of the ’570 patent is attached hereto as Exhibit E.

36. CMP owns all rights, title, and interests in each of the Patents-in-Suit.

37. CaroSpir® or the use of CaroSpir® is covered by at least one claim of each of the Patents-in-Suit.

INFRINGEMENT BY AMNEAL

38. By letter dated March 4, 2021 (“First Notice Letter”), Amneal notified CMP that it had submitted ANDA No. 215572 to the FDA under Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act (“FDCA”) (21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95(c)) seeking approval to engage in the commercial manufacture, use, and/or sale of a generic version of CaroSpir® before the expiration of the Patents-in-Suit except for the ’570 patent.

39. By letter dated March 25, 2021 (“Second Notice Letter”), Amneal notified CMP that it had submitted ANDA No. 215572 to the FDA under Section 505(j)(2)(B) of the Federal

Food, Drug, and Cosmetic Act ("FDCA") (21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95(c)) seeking approval to engage in the commercial manufacture, use, and/or sale of a generic version of CaroSpir® before the expiration of the '570 patent.

40. The Amneal ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification"), alleging that the claims of the Patents-in-Suit are invalid, unenforceable and/or would not be infringed by the Amneal ANDA Product.

41. Amneal intends to engage in commercial manufacture, use, and/or sale of the Amneal ANDA Product promptly upon receiving FDA approval to do so.

42. By submitting ANDA No. 215572, Amneal has represented to FDA that the Amneal ANDA Product has the same active ingredient, the same route of administration, the same dosage form, the same use, the same strength, and is bioequivalent to CaroSpir®.

43. The Amneal ANDA Product, upon approval, will have the same active ingredient as CaroSpir® in the same amount as CaroSpir®, which is 25 mg/5 mL spironolactone.

44. The Amneal ANDA Product, upon approval, will be in the same dosage form as CaroSpir®, which is an oral suspension.

45. The Amneal ANDA Product, upon approval, will have the same or substantially similar inactive ingredients as CaroSpir®.

46. The Amneal ANDA Product, upon approval, will have the following inactive ingredients: sorbic acid, potassium sorbate, citric acid anhydrous, sodium citrate, dihydrate, simethicone emulsion, saccharin sodium, xanthan gum, Magnasweet 110, glycerin, banana flavor, and purified water.

47. Assuming any inactive ingredient listed in paragraph 46 of this Complaint is not included in the Amneal ANDA Product, that product, upon approval, will have in place of that

inactive ingredient an inactive ingredient that is substantially similar to the missing inactive ingredient, and which performs the same function as the missing inactive ingredient, in the same way, giving the same result within the oral suspension.

48. Upon information and belief, the Amneal ANDA Product, upon approval, will have xanthan gum as one of its inactive ingredients.

49. The Amneal ANDA Product, upon approval, will be sold with FDA-approved prescribing information that informs patients and/or physicians treating those patients that the product is to be used by oral administration.

50. The Amneal ANDA Product, upon approval, will be a ready-to-use oral suspension with spironolactone as the active ingredient.

51. The Amneal ANDA Product, upon approval, will be available as an option for patients needing spironolactone and who have dysphagia, who have difficulty swallowing, or who cannot swallow tablets.

52. The Amneal ANDA Product, upon approval, will not require compounding before administration.

53. The Amneal ANDA Product, upon approval, will be approved for the same uses for which CaroSpir® has been approved by the FDA.

54. The Amneal ANDA Product, upon approval, will be bioequivalent to CaroSpir®.

55. Amneal has administered the Amneal ANDA Product by oral administration to humans in order to establish that its product is bioequivalent to CaroSpir®.

56. This action is being filed within forty-five (45) days of CMP's receipt of the Notice Letter and the Second Notice Letter.

CLAIMS FOR RELIEF

Count I—Infringement of '394 patent

57. CMP incorporates each of the preceding paragraphs as if fully set forth herein.

58. Amneal had actual and constructive knowledge of the '394 patent prior to submitting ANDA No. 215572, and was aware that submission of the Amneal ANDA to FDA constituted an act of infringement of the '394 patent under 35 U.S.C. § 271(e)(2)(A).

59. Amneal's submission of the Amneal ANDA to FDA with the corresponding certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) as to the '394 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

60. Upon approval, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Amneal ANDA Product will infringe one or more claims of the '394 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing the Amneal ANDA Product, and/or by actively inducing infringement by others under 35 U.S.C. § 271(b) and/or contributing to infringement under 35 U.S.C. § 271(c), unless this Court orders that the effective date of any FDA approval of the Amneal ANDA shall be no earlier than the expiration of the '394 patent.

61. In addition, on information and belief, Amneal had specific intent to infringe the '394 patent when it filed ANDA No. 215572.

62. There are no substantial non-infringing uses for the Amneal ANDA Product other than as claimed in the '394 patent.

63. The commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Product in violation of CMP's patent rights will cause substantial and irreparable harm to CMP for which CMP does not have an adequate remedy at law.

Count II—Infringement of the '083 patent

64. CMP incorporates each of the preceding paragraphs as if fully set forth herein.

65. Amneal had actual and constructive knowledge of the '083 patent prior to submitting ANDA No. 215572, and was aware that submission of the Amneal ANDA to FDA constituted an act of infringement of the '083 patent under 35 U.S.C. § 271(e)(2)(A).

66. Amneal's submission of the Amneal ANDA to FDA with the corresponding certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) as to the '083 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

67. Upon approval, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Amneal ANDA Product will infringe one or more claims of the '083 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing the Amneal ANDA Product, and/or by actively inducing infringement by others under 35 U.S.C. § 271(b) and/or contributing to infringement under 35 U.S.C. § 271(c), unless this Court orders that the effective date of any FDA approval of the Amneal ANDA shall be no earlier than the expiration of the '083 patent.

68. In addition, on information and belief, Amneal had specific intent to infringe the '083 patent when it filed ANDA No. 215572.

69. The commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Product in violation of CMP's patent rights will cause substantial and irreparable harm to CMP for which CMP does not have an adequate remedy at law.

Count III—Infringement of the '906 patent

70. CMP incorporates each of the preceding paragraphs as if fully set forth herein.

71. Amneal had actual and constructive knowledge of the '906 patent prior to submitting ANDA No. 215572, and was aware that submission of the Amneal ANDA to FDA constituted an act of infringement of the '906 patent under 35 U.S.C. § 271(e)(2)(A).

72. Amneal's submission of the Amneal ANDA to FDA with the corresponding certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) as to the '906 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

73. Upon approval, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Amneal ANDA Product will infringe one or more claims of the '906 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing the Amneal ANDA Product, and/or by actively inducing infringement by others under 35 U.S.C. § 271(b) and/or contributing to infringement under 35 U.S.C. § 271(c), unless this Court orders that the effective date of any FDA approval of the Amneal ANDA shall be no earlier than the expiration of the '906 patent.

74. In addition, on information and belief, Amneal had specific intent to infringe the '906 patent when it filed ANDA No. 215572.

75. The commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Product in violation of CMP's patent rights will cause substantial and irreparable harm to CMP for which CMP does not have an adequate remedy at law.

Count IV—Infringement of the '907 patent

76. CMP incorporates each of the preceding paragraphs as if fully set forth herein.

77. Amneal had actual and constructive knowledge of the '907 patent prior to submitting ANDA No. 215572, and was aware that submission of the Amneal ANDA to FDA constituted an act of infringement of the '907 patent under 35 U.S.C. § 271(e)(2)(A).

78. Amneal's submission of the Amneal ANDA to FDA with the corresponding certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) as to the '907 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

79. Upon approval, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Amneal ANDA Product will infringe one or more claims of the '907 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing the Amneal ANDA Product, and/or by actively inducing infringement by others under 35 U.S.C. § 271(b) and/or contributing to infringement under 35 U.S.C. § 271(c), unless this Court orders that the effective date of any FDA approval of the Amneal ANDA shall be no earlier than the expiration of the '907 patent.

80. In addition, on information and belief, Amneal had specific intent to infringe the '907 patent when it filed ANDA No. 215572.

81. The commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Product in violation of CMP's patent rights will cause substantial and irreparable harm to CMP for which CMP does not have an adequate remedy at law.

Count V—Infringement of the '570 patent

82. CMP incorporates each of the preceding paragraphs as if fully set forth herein.

83. Amneal had actual and constructive knowledge of the '570 patent prior to submitting ANDA No. 215572, and was aware that submission of the Amneal ANDA to FDA constituted an act of infringement of the '570 patent under 35 U.S.C. § 271(e)(2)(A).

84. Amneal's submission of the Amneal ANDA to FDA with the corresponding certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) as to the '570 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

85. Upon approval, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Amneal ANDA Product will infringe one or more claims of the '570 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing the Amneal ANDA Product, and/or by actively inducing infringement by others under 35 U.S.C. § 271(b) and/or contributing to infringement under 35 U.S.C. § 271(c), unless this Court orders that the effective date of any FDA approval of the Amneal ANDA shall be no earlier than the expiration of the '570 patent and any additional periods of regulatory exclusivity associated therewith.

86. In addition, on information and belief, Amneal had specific intent to infringe the '570 patent when it filed ANDA No. 215572.

87. The commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Product in violation of CMP's patent rights will cause substantial and irreparable harm to CMP for which CMP does not have an adequate remedy at law.

PRAYER FOR RELIEF

CMP respectfully requests the following relief:

a) A judgment that Amneal has infringed the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 215572 under Section 505(j) of the FDCA, and that

Amneal's making, using, offering to sell, or selling in the United States or importing into the United States of the Amneal ANDA Product will infringe one or more claims of the Patents-in-Suit.

b) An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 215572 shall be a date which is not earlier than the latest expiration date of the Patents-in-Suit, as extended by any applicable periods of exclusivity;

c) An order under 35 U.S.C. § 27l(e)(4)(B) permanently enjoining Amneal, its subsidiaries, parents, officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture use, offer to sell, or importation into the United States, of any drug product the use of which is covered by the Patents-in-Suit, including the Amneal ANDA Product;

d) A finding that this is an exceptional case under 35 U.S.C. § 285, and that CMP be awarded reasonable attorneys' fees and costs; and

e) An award of any such other and further relief as the Court may deem just and proper.

/s/ Kelly E. Farnan

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