IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CMP DEVELOPMENT, LLC, Plaintiff, v. HETERO USA, INC., HETERO LABS LIMITED UNIT-III and HETERO LABS LIMITED, Defendants.	)	C.A. No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff CMP Development, LLC ("CMP"), by and through its attorneys, for its Complaint against Defendants Hetero USA Inc., Hetero Labs Limited Unit - III, and Hetero Labs Limited (collectively "Hetero"), 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"), 10,888,570 ("the '570 patent"), 11,389,461 ("the '461 patent"), 11,395,828 ("the '828 patent"), and 11,491,166 ("the '166 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 Hetero of Abbreviated New Drug Application No. 218085 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 Hetero ANDA").

3. The Hetero 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 "Hetero 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 Hetero'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. On information and belief, Hetero USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854. On information and belief, Hetero USA, Inc. is the United States Regulatory Agent for Hetero Labs Limited Unit - III, a division of Hetero Labs Limited.

7. On information and belief, defendant Hetero Labs Limited Unit - III ("Hetero Unit - III") is a company organized and existing under the laws of India, having a principal place of business at #22-110, IDA Jeedimetla, Hyderabad – 500 055, Telangana, India. On information and belief, Hetero Unit - III is a division of Hetero Labs Limited. On information and belief, Hetero Unit - III itself and through its affiliates and subsidiaries, including Hetero USA and Hetero Labs Limited, formulates, manufactures, packages, and markets generic versions of branded pharmaceutical drugs for distribution in the District of Delaware and throughout the United States.

8. On information and belief, defendant Hetero Labs Limited ("Hetero Labs") is a company organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Telengana, India. On information and belief, Hetero Labs is the parent company of Hetero USA and Hetero Unit -

III. On information and belief, Hetero Labs itself and through its affiliates and subsidiaries, including Hetero USA and Hetero Unit - III, formulates, manufactures, packages, and markets generic versions of branded pharmaceutical drugs for distribution in the District of Delaware and throughout the United States.

9. On information and belief, Hetero USA, Inc. 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.

10. On further information and belief, Hetero USA, Inc. Hetero Labs, and Hetero Unit - III collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products in the United States.

11. On further information and belief, Hetero USA, Inc. Hetero Labs, and Hetero Unit - III are agents of each other and/or operate in concert as integrated parts of the same business group and enter into agreements with each other that are nearer than arm's length.

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

JURISDICTION AND VENUE

13. 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 Hetero ANDA.

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

15. This Court has personal jurisdiction over Hetero and its affiliates and subsidiaries because of, among other things, Hetero's persistent and continuous contacts with Delaware.

Hetero 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.

16. Hetero USA is a corporation formed under the laws of the State of Delaware and is registered to do business in Delaware.

17. Hetero regularly and continuously transacts business in Delaware, including by selling pharmaceutical products in Delaware.

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

19. This judicial district is a likely destination of the product that is the subject of the Hetero ANDA.

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

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

22. Hetero intends to direct sales of its generic drugs in this judicial district once Hetero receives the requested FDA approval to market the Hetero 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.

23. Hetero will engage in marketing of its Hetero ANDA Product in Delaware upon approval of the Hetero ANDA.

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

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

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

CMP'S CAROSPIR® PRODUCT

27. 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®").

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

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

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

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

32. 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.

33. 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

34. Pursuant to 21 U.S.C. § 355, the '394, '083, '906, '907, '570, '461, '828, and '166 patents are listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book") in connection with the CaroSpir® product.

35. 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.

36. 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.

37. 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.

38. 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.

39. 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.

40. The ’461 patent, entitled “Spironolactone Aqueous Compositions,” was duly and lawfully issued by the USPTO on July 19, 2022. A true and correct copy of the ’461 patent is attached hereto as Exhibit F.

41. The ’828 patent, entitled “Spironolactone Aqueous Compositions,” was duly and lawfully issued by the USPTO on July 26, 2022. A true and correct copy of the ’828 patent is attached hereto as Exhibit G.

42. The '166 patent, entitled "Spironolactone Aqueous Compositions," was duly and lawfully issued by the USPTO on November 8, 2022. A true and correct copy of the '166 patent is attached hereto as Exhibit H.

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

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

INFRINGEMENT BY HETERO

45. By letter dated June 6, 2023 ("Notice Letter"), Hetero notified CMP that it had submitted ANDA No. 218085 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.

46. The Hetero 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 Hetero ANDA Product.

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

48. By submitting ANDA No. 218085, Hetero has represented to the FDA that the Hetero ANDA Product has the same active ingredient, the same route of administration, the same dosage form, the same use, the same strength, and bioequivalence to CaroSpir®.

49. The Hetero 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.

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

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

52. Upon information and belief, the Hetero 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.

53. Assuming any inactive ingredient listed in paragraph 52 of this Complaint is not included in the Hetero 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.

54. Upon information and belief, the Hetero ANDA Product, upon approval, will have xanthan gum or an equivalent of xanthan gum that functions in the Hetero ANDA Product as a suspending agent.

55. The Hetero 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 for oral administration.

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

57. The Hetero 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.

58. The Hetero ANDA Product, upon approval, will not require compounding before administration.

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

60. Upon information and belief, the Hetero ANDA Product, upon approval, will be bioequivalent to CaroSpir®.

61. Upon information and belief, Hetero has orally administered the Hetero ANDA Product by to humans in order to establish that its product is bioequivalent to CaroSpir®.

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

CLAIMS FOR RELIEF

Count I—Infringement of '394 patent

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

64. Hetero had actual and constructive knowledge of the '394 patent prior to submitting ANDA No. 218085 and was aware that submission of the Hetero ANDA to FDA constituted an act of infringement of the '394 patent under 35 U.S.C. § 271(e)(2)(A).

65. Hetero's submission of the Hetero 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).

66. Upon approval, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Hetero 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 Hetero 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 Hetero ANDA shall be no earlier than the expiration of the '394 patent.

67. In addition, on information and belief, Hetero had specific intent to infringe the '394 patent when it filed ANDA No. 218085.

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

69. The commercial manufacture, use, offer for sale, sale, and/or importation of the Hetero 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

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

71. Hetero had actual and constructive knowledge of the '083 patent prior to submitting ANDA No. 218085 and was aware that submission of the Hetero ANDA to FDA constituted an act of infringement of the '083 patent under 35 U.S.C. § 271(e)(2)(A).

72. Hetero's submission of the Hetero 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).

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 Hetero 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 Hetero ANDA Product, unless this Court orders that the effective date of any FDA approval of the Hetero ANDA shall be no earlier than the expiration of the '083 patent.

74. In addition, on information and belief, Hetero had specific intent to infringe the '083 patent when it filed ANDA No. 218085.

75. The commercial manufacture, use, offer for sale, sale, and/or importation of the Hetero 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

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

77. Hetero had actual and constructive knowledge of the '906 patent prior to submitting ANDA No. 218085 and was aware that submission of the Hetero ANDA to FDA constituted an act of infringement of the '906 patent under 35 U.S.C. § 271(e)(2)(A).

78. Hetero's submission of the Hetero 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).

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 Hetero 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 Hetero ANDA Product, unless this Court orders that the effective date of any FDA approval of the Hetero ANDA shall be no earlier than the expiration of the '906 patent.

80. In addition, on information and belief, Hetero had specific intent to infringe the '906 patent when it filed ANDA No. 218085.

81. The commercial manufacture, use, offer for sale, sale, and/or importation of the Hetero 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

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

83. Hetero had actual and constructive knowledge of the '907 patent prior to submitting ANDA No. 218085 and was aware that submission of the Hetero ANDA to FDA constituted an act of infringement of the '907 patent under 35 U.S.C. § 271(e)(2)(A).

84. Hetero's submission of the Hetero 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).

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 Hetero 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 Hetero ANDA Product, unless this Court orders that the effective date of any FDA approval of the Hetero ANDA shall be no earlier than the expiration of the '907 patent.

86. In addition, on information and belief, Hetero had specific intent to infringe the '907 patent when it filed ANDA No. 218085.

87. The commercial manufacture, use, offer for sale, sale, and/or importation of the Hetero 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

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

89. Hetero had actual and constructive knowledge of the '570 patent prior to submitting ANDA No. 218085 and was aware that submission of the Hetero ANDA to FDA constituted an act of infringement of the '570 patent under 35 U.S.C. § 271(e)(2)(A).

90. Hetero's submission of the Hetero 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).

91. Upon approval, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Hetero 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 Hetero ANDA Product, unless this Court orders that the effective date of any FDA approval of the Hetero ANDA shall be no earlier than the expiration of the '570 patent and any additional periods of regulatory exclusivity associated therewith.

92. In addition, on information and belief, Hetero had specific intent to infringe the '570 patent when it filed ANDA No. 218085.

93. The commercial manufacture, use, offer for sale, sale, and/or importation of the Hetero 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 VI—Infringement of the '461 patent

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

95. Hetero had actual and constructive knowledge of the '461 patent prior to submitting ANDA No. 218085 and was aware that submission of the Hetero ANDA to FDA constituted an act of infringement of the '461 patent under 35 U.S.C. § 271(e)(2)(A).

96. Hetero's submission of the Hetero 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 '461 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

97. Upon approval, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Hetero ANDA Product will infringe one or more claims of the '461 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 Hetero ANDA Product, dunless this Court orders that the effective date of any FDA approval of the Hetero ANDA shall be no earlier than the expiration of the '461 patent and any additional periods of regulatory exclusivity associated therewith.

98. In addition, on information and belief, Hetero had specific intent to infringe the '461 patent when it filed ANDA No. 218085.

99. The commercial manufacture, use, offer for sale, sale, and/or importation of the Hetero 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 VII—Infringement of the '828 patent

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

101. Hetero had actual and constructive knowledge of the '828 patent prior to submitting ANDA No. 218085 and was aware that submission of the Hetero ANDA to FDA constituted an act of infringement of the '828 patent under 35 U.S.C. § 271(e)(2)(A).

102. Hetero's submission of the Hetero 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 '828 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

103. Upon approval, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Hetero ANDA Product will infringe one or more claims of the '828 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 Hetero 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 Hetero ANDA shall be no earlier than the expiration of the '828 patent and any additional periods of regulatory exclusivity associated therewith.

104. In addition, on information and belief, Hetero had specific intent to infringe the '828 patent when it filed ANDA No. 218085.

105. The commercial manufacture, use, offer for sale, sale, and/or importation of the Hetero 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 VIII—Infringement of the '166 patent

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

107. Hetero had actual and constructive knowledge of the '166 patent prior to submitting ANDA No. 218085 and was aware that submission of the Hetero ANDA to FDA constituted an act of infringement of the '166 patent under 35 U.S.C. § 271(e)(2)(A).

108. Hetero's submission of the Hetero 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 '166 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

109. Upon approval, the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States of the Hetero ANDA Product will infringe one or more claims of the '166 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 Hetero ANDA Product, unless this Court orders that the effective date of any FDA approval of the Hetero ANDA shall be no earlier than the expiration of the '166 patent and any additional periods of regulatory exclusivity associated therewith.

110. In addition, on information and belief, Hetero had specific intent to infringe the '166 patent when it filed ANDA No. 2218085.

111. The commercial manufacture, use, offer for sale, sale, and/or importation of the Hetero 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 Hetero has infringed the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 218085 under Section 505(j) of the FDCA, and that

Hetero's making, using, offering to sell, or selling in the United States or importing into the United States of the Hetero 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. 218085 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 Hetero, 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 Hetero 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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