IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and SUNOVION PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	C.A. No. 20-780-CFC
v.	)	
HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, and HETERO USA INC.,	)	
Defendants.	)	

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and Sunovion Pharmaceuticals Inc. (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Defendants Hetero Labs Limited ("Hetero Labs"), Hetero Labs Limited Unit-V ("Hetero Unit-V"), and Hetero USA Inc. ("Hetero USA") (collectively, "Hetero"), allege as follows:

THE PARTIES

1. BIAL - PORTELA & CA S.A. is a Portuguese corporation having its principal place of business at Av da Siderurgia Nacional, Coronado (São Romão and São Mamede), 4745 455 São Mamede do Coronado, Portugal.

2. BIAL - HOLDING, S.A. is a Portuguese corporation having its principal place of business at Av da Siderurgia Nacional, Coronado (São Romão and São Mamede), 4745 365 Trofa, Portugal.

3. BIAL - PORTELA & CA S.A. and BIAL - HOLDING, S.A. (collectively, "Bial") are in the business of developing innovative therapies for epilepsy, partial-onset seizures, and other related neurological conditions. Bial's asserted patent(s) cover APTIOM®, which is marketed and

sold in this judicial district and throughout the United States by Sunovion Pharmaceuticals Inc. for treating partial-onset seizures in patients 4 years of age and older.

4. Sunovion Pharmaceuticals Inc. ("Sunovion") is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

5. On information and belief, Hetero Labs is a corporation organized and existing under the laws of India, with its principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

6. On information and belief, Hetero Labs is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including the State of Delaware.

7. On information and belief, Hetero Unit-V is a corporation organized and existing under the laws of India, with its principal place of business at Polepally, Jadcherla, Mahabubnagar, 509301, Andhra Pradesh, India.

8. On information and belief, Hetero Unit-V is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including the State of Delaware, in concert with Hetero Labs and Hetero USA.

9. On information and belief, Hetero Unit-V is a division of Hetero Labs.

10. On information and belief, Hetero USA is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

11. On information and belief, Hetero USA is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in the State of Delaware, in concert with Hetero Labs and Hetero Unit-V.

12. On information and belief, Hetero USA is a wholly owned subsidiary of Hetero Labs.

13. On information and belief, the acts of Hetero complained of herein were done with the cooperation, participation, and assistance of Hetero Labs, Hetero Unit-V, and Hetero USA.

14. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg Abbreviated New Drug Application ("ANDA") No. 211186, Hetero Labs, Hetero Unit-V, and Hetero USA will act in concert to distribute and sell the generic product described in Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg ANDA No. 211186 ("Hetero's Generic Product") throughout the United States, including the State of Delaware.

NATURE OF THE ACTION

15. This is a civil action for patent infringement of U.S. Patent Nos. 10,675,287 ("the '287 patent"), 10,695,354 ("the '354 patent"), and 10,702,536 ("the '536 patent") (collectively, "the patents-in-suit") arising under the United States Patent Laws, Title 35, United States Code, § 1, *et. seq.*, and in particular under 35 U.S.C. § 271. This action relates to ANDA No. 211186, which Hetero filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA"), for approval to market in the United States a generic copy of Plaintiffs' APTIOM® product prior to the expiration of the patents-in-suit.

16. Hetero has infringed one or more claims of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 211186 seeking FDA approval for the

commercial manufacture, use, import, offer for sale, and/or sale in the United States of generic APTIOM® (eslicarbazepine acetate) Tablets for the treatment of patients with partial-onset seizures prior to the expiration of the patents-in-suit, or any extensions thereof. Hetero will infringe one or more claims of the patents-in-suit under 35 U.S.C. § 271(a), (b), or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of generic APTIOM® (eslicarbazepine acetate) Tablets for the treatment of patients with partial-onset seizures prior to the expiration of the patents-in-suit, or any extensions thereof.

17. Plaintiffs previously filed a separate action in this Court against Hetero for patent infringement, which included counts for infringement of U.S. Patent Nos. 9,750,747 ("the '747 patent"), 8,372,431 ("the '431 patent"), 9,206,135 ("the '135 patent"), 9,566,244 ("the '244 patent"), 9,643,929 ("the '929 patent"), and 9,763,954 ("the '954 patent). *Bial - Portela & CA S.A., et al. v. Hetero Labs Limited, et al.*, C.A. No. 18-342-CFC (the "First Suit") was filed on March 2, 2018. The First Suit was filed in response to a letter from Hetero dated January 18, 2018 ("Hetero's Notice Letter"), purporting to be a "Notice of Certification" for ANDA No. 211186 pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 as to the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent, and the '954 patent. The First Suit included counts for infringement of the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent, and the '954 patent.

18. The First Suit did not include counts for infringement of U.S. Patent No. 5,753,646 ("the '646 patent"), which will expire on June 27, 2021, because Hetero's Notice Letter did not assert noninfringement or invalidity of the '646 patent. Based on information and belief, Hetero is maintaining its certification as to the '747 patent, the '431 patent, the '135 patent, the '244 patent,

the ’929 patent, and the ’954 patent set out in Hetero’s Notice Letter. Thus, Plaintiffs will continue to prosecute all infringement counts presented in the First Suit.

JURISDICTION AND VENUE

19. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

20. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

21. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

22. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because Hetero USA is incorporated in the State of Delaware, and Hetero Labs and Hetero Unit-V are incorporated in India and may be sued in any judicial district in the United States in which they are subject to the court’s personal jurisdiction.

23. This Court has personal jurisdiction over Hetero Labs, *inter alia*, under Federal Rule of Civil Procedure 4(k)(2), because Hetero Labs is organized under the laws of India.

24. This Court has personal jurisdiction over Hetero Labs *inter alia*, under Federal Rule of Civil Procedure 4(k)(2), because Hetero Labs is organized under the laws of India.

25. This Court has personal jurisdiction over Hetero USA because, *inter alia*, Hetero USA is organized and existing under the laws of the State of Delaware.

26. Upon information and belief, Hetero USA maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, W/K Incorporating Services, Inc., located at 3500 South DuPont Highway, Dover, DE 19901.

27. This Court also has personal jurisdiction over Hetero because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, Hetero satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State), § 3104(c)(4) "[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State"), and § 3104(c)(5) ("[h]as an interest in, uses or possesses real property in the State").

28. This Court also has personal jurisdiction over Hetero because, *inter alia*, this action arises from activities of Hetero directed toward Delaware.

29. Upon information and belief, the effort to seek approval for ANDA No. 211186 and to manufacture, import, market, and/or sell Hetero's Generic Product upon approval has been a cooperative and joint enterprise and venture between Hetero Labs, Hetero Unit-V, and Hetero USA.

30. Upon information and belief, Hetero Labs, Hetero Unit-V, and Hetero USA have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing, filing and maintaining ANDA No. 211186 and in commercializing Hetero's Generic Product in the United States, including in this judicial district, in accordance with ANDA 211186 upon approval.

31. Upon information and belief, Hetero Labs, Hetero Unit-V, and Hetero USA have thus been, and continue to be, joint and prime actors in the drafting, submission, approval and maintenance of ANDA No. 211186.

32. This Court has personal jurisdiction over Hetero by virtue of the fact that, *inter alia*, Hetero has committed—or aided, abetted, induced, contributed to, or participated in the commission of—the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs.

33. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of ANDA No. 211186, Hetero will market, distribute, and sell Hetero's Generic Product described in ANDA No. 211186 throughout the United States, including in Delaware.

34. This Court also has personal jurisdiction over Hetero because, *inter alia*, Hetero has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Hetero, either directly or through affiliates, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. Hetero's website, https://www.heteroworld.com/index.php, states that its "Hetero has a strong global presence in over 126 countries and focusses on making affordable medicines accessible to patients worldwide" and that "Hetero is one of the largest exporter of therapeutic drugs to … America." *See* https://www.heteroworld.com/company-profile.php; https://www.heteroworld.com/products.php (accessed June 8, 2020). 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 the State of Delaware.

35. This Court also has personal jurisdiction over Hetero because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. For example, Hetero has previously invoked this Court's jurisdiction by asserting counterclaims in at least 8

other cases. *See*, *e.g.*, 17-cv-00825, 17-cv-00376, 16-cv-00928, 16-cv-00452, 15-cv-00179, 14-cv-00543, 14-cv-00421, and 14-cv-00166.

36. This Court also has personal jurisdiction over Hetero because Hetero did not contest jurisdiction in the First Suit.

37. For these reasons and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Hetero.

FACTUAL BACKGROUND

The NDA

38. Sunovion is the holder of New Drug Application ("NDA") No. 022416 for APTIOM® (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms.

39. The FDA approved NDA No. 022416 on November 8, 2013 for use as adjunctive therapy of partial-onset seizures.

40. The FDA approved NDA No. 022416 on August 27, 2015 for use as monotherapy of partial-onset seizures.

41. The FDA approved NDA No. 022416 on September 13, 2017 for pediatric patients 4 years of age and older.

42. APTIOM® Tablets are prescription drugs approved for the treatment of partial-onset seizures in patients 4 years of age and older. Eslicarbazepine acetate is the active ingredient in the APTIOM® Tablets.

The Patents-in-Suit

43. The '287 patent, titled "Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate," was duly and legally issued by the United States Patent and Trademark Office on June 9, 2020. A true and correct copy of the '287 patent is attached as Exhibit A.

44. BIAL - PORTELA & CA S.A. owns the rights to the ’287 patent. Sunovion is the exclusive licensee in the United States of the ’287 patent. The ’287 patent will expire on May 6, 2025.

45. The ’287 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

46. The ’287 patent covers methods for treating a patient with partial-onset seizures by administering once-daily about 1200 mg of eslicarbazepine acetate.

47. The prescribing information for APTIOM®, instructs physicians to administer APTIOM® Tablets once-daily for the treatment of partial-onset seizures in patients 4 years of age and older in a dosage of about 1200 mg of eslicarbazepine acetate.

48. Thus, the once-daily use of APTIOM® (Eslicarbazepine Acetate) Tablets in a dosage of about 1200 mg and any generic eslicarbazepine acetate tablets in a dosage of about 1200 mg for the treatment of patients with partial-onset seizures is covered by the ’287 patent, and Plaintiffs have the right to enforce the ’287 patent.

49. The ’354 patent, titled “Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate,” was duly and legally issued by the United States Patent and Trademark Office on June 30, 2020. A true and correct copy of the ’354 patent is attached as Exhibit B.

50. BIAL - PORTELA & CA S.A. owns the rights to the ’354 patent. Sunovion is the exclusive licensee in the United States of the ’354 patent. The ’354 patent will expire on May 6, 2025.

51. The ’354 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

52. The ’354 patent covers methods for treating a patient with partial-onset seizures by administering eslicarbazepine acetate once-daily.

53. The prescribing information for APTIOM®, instructs physicians to administer APTIOM® Tablets once-daily for the treatment of partial-onset seizures in patients 4 years of age and older.

54. Thus, the once-daily use of APTIOM® (Eslicarbazepine Acetate) Tablets and any generic eslicarbazepine acetate tablets for the treatment of patients with partial-onset seizures is covered by the ’354 patent, and Plaintiffs have the right to enforce the ’354 patent.

55. The ’536 patent, titled “Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate,” was duly and legally issued by the United States Patent and Trademark Office on July 7, 2020. A true and correct copy of the ’536 patent is attached as Exhibit C.

56. BIAL - PORTELA & CA S.A. owns the rights to the ’536 patent. Sunovion is the exclusive licensee in the United States of the ’536 patent. The ’536 patent will expire on May 6, 2025.

57. Information regarding the ’536 patent was submitted to the FDA for listing in the Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

58. The ’536 patent covers methods for treating a patient with partial-onset seizures by administering eslicarbazepine acetate once-daily.

59. The prescribing information for APTIOM®, instructs physicians to administer APTIOM® Tablets once-daily for the treatment of partial-onset seizures in patients 4 years of age and older.

60. Thus, the once-daily use of APTIOM® (Eslicarbazepine Acetate) Tablets and any generic eslicarbazepine acetate tablets for the treatment of patients with partial-onset seizures is covered by the ’536 patent, and Plaintiffs have the right to enforce the ’536 patent.

The ANDA

61. On information and belief, Hetero filed ANDA No. 211186 with the FDA under 21 U.S.C. § 355(j) before January 18, 2018, to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms, which are generic versions of Plaintiffs’ APTIOM® (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms.

62. Hetero’s Notice Letter alleged that the claims of the ’747 patent, the ’431 patent, the ’135 patent, the ’244 patent, the ’929 patent, and the ’954 patent are invalid and/or will not be infringed by the activities described in Hetero’s ANDA No. 211186. Hetero’s Notice Letter also informed Plaintiffs that Hetero seeks approval to market Hetero’s Generic Product before the ’747, ’431, ’135, ’244, ’929, and ’954 patents expire.

63. The ’135 and ’929 patents expire on April 21, 2026. The patents-in-suit will expire on May 6, 2025.

64. Hetero’s ANDA No. 211186 has been pending before the FDA since at least January 18, 2018, the date of Hetero’s Notice Letter to Plaintiffs.

65. On information and belief, following FDA approval of Hetero’s ANDA No. 211186, Hetero will make, use, sell, or offer to sell Hetero’s Generic Product throughout the United States, or import such generic products into the United States before the patents-in-suit expire.

COUNT I

(INFRINGEMENT OF THE ’287 PATENT UNDER 35 U.S.C. § 271(e)(2))

66. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

67. On information and belief, Hetero filed ANDA No. 211186 in order to obtain approval to manufacture, use, import, offer to sell and/or sell Hetero's Generic Product in the United States before the expiration of the '287 patent.

68. On information and belief, in its ANDA No. 211186, Hetero has represented to the FDA that Hetero's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

69. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211186 seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Product before the expiration date of the '287 patent, constitutes infringement, either literally or under the doctrine of equivalents.

70. Upon FDA approval of ANDA No. 211186, Hetero will infringe one or more claims of the '287 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 211186 shall be no earlier than the expiration of the '287 patent and any additional periods of exclusivity.

71. On information and belief, Hetero knows, or should know, and intends that physicians will prescribe and patients will take Hetero's Generic Product for which approval is sought in ANDA No. 211186, and therefore will infringe at least one claim in the '287 patent.

72. On information and belief, Hetero had knowledge of the '287 patent and, by its promotional activities and proposed package insert for Hetero's Generic Product, knows or should

know that it will induce direct infringement of at least one of the claims of the ’287 patent, either literally or under the doctrine of equivalents.

73. On information and belief, Hetero is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Hetero’s Generic Product according to the instructions in the proposed package insert in a way that directly infringes the ’287 patent.

74. The offering to sell, sale, making, and/or importation of Hetero’s Generic Product would actively induce infringement of at least one of the claims of the ’287 patent, either literally or under the doctrine of equivalents. Hetero has knowledge and is aware of Plaintiffs’ ’287 patent.

75. On information and belief, if ANDA No. 211186 is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero’s Generic Product.

76. Hetero has had and continues to have knowledge that Hetero’s Generic Product is especially adapted for a use that infringes the ’287 patent.

77. On information and belief, Hetero has had and continues to have knowledge that there is no substantial non-infringing use for Hetero’s Generic Product.

78. On information and belief, Hetero’s actions relating to Hetero’s ANDA No. 211186 complained of herein were done by and for the benefit of Hetero.

79. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing or actively inducing infringement of at least one claim of the ’287 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT II

(DECLARATORY JUDGEMENT OF INFRINGEMENT OF THE ’287 PATENT)

80. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

81. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

82. There is an actual and justiciable controversy between Plaintiffs and Hetero concerning infringement of the ’287 patent of sufficient immediacy and reality such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

83. Hetero has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Hetero’s Generic Product prior to expiration of the ’287 patent.

84. Hetero’s actions, including, but not limited to, submitting, or causing to be submitted to the FDA, ANDA No. 211186 seeking approval to manufacture, use, import, offer to sell and sell Hetero’s Generic Product before the expiration date of the ’287 patent and engaging in litigation, indicate a refusal to change the course of their actions in the face of knowledge of the ’287 patent and acts by Plaintiffs.

85. On information and belief, the FDA could approve Hetero’s ANDA No. 211186 prior to expiration of the ’287 patent and as early as the expiration of the ’646 patent and conclusion of the First Suit, which is currently scheduled for trial in January 2021.

86. On information and belief, Hetero intends to manufacture, use, import, offer to sell and/or sell Hetero’s Generic Product upon FDA approval of ANDA No. 211186.

87. Upon FDA approval of ANDA No. 211186, Hetero will infringe one or more claims of the ’287 patent, either literally or under the doctrine of equivalents under § 271(a) by making,

using, offering to sell, selling, and/or importing Hetero's Generic Product, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c).

88. On information and belief, Hetero knows, or should know, and intends that physicians will prescribe and patients will take Hetero's Generic Product for which approval is sought in ANDA No. 211186, and therefore will infringe at least one claim in the '287 patent.

89. On information and belief, Hetero had knowledge of the '287 patent and, by its promotional activities and proposed package insert for Hetero's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '287 patent, either literally or under the doctrine of equivalents.

90. On information and belief, Hetero is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Hetero's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '287 patent.

91. The offering to sell, sale, making, and/or importation of Hetero's Generic Product would actively induce infringement of at least one of the claims of the '287 patent, either literally or under the doctrine of equivalents. Hetero has knowledge and is aware of Plaintiffs' '287 patent.

92. On information and belief, if ANDA No. 211186 is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero's Generic Product.

93. Hetero has had and continues to have knowledge that Hetero's Generic Product is especially adapted for a use that infringes the '287 patent.

94. On information and belief, Hetero has had and continues to have knowledge that there is no substantial non-infringing use for Hetero's Generic Product.

95. On information and belief, Hetero's actions relating to Hetero's ANDA No. 211186 complained of herein were done by and for the benefit of Hetero.

96. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing or actively inducing infringement of at least one claim of the '287 patent.

97. Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

98. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Hetero's Generic Product prior to expiration of the '287 patent by Hetero will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '287 patent.

COUNT III

(INFRINGEMENT OF THE '354 PATENT UNDER 35 U.S.C. § 271(e)(2))

99. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

100. On information and belief, Hetero filed ANDA No. 211186 in order to obtain approval to manufacture, use, import, offer to sell and/or sell Hetero's Generic Product in the United States before the expiration of the '354 patent.

101. On information and belief, in its ANDA No. 211186, Hetero has represented to the FDA that Hetero's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

102. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211186 seeking approval for the commercial manufacture, use, or sale of Hetero's Generic Product before

the expiration date of the ’354 patent, constitutes infringement, either literally or under the doctrine of equivalents.

103. Upon FDA approval of ANDA No. 211186, Hetero will infringe one or more claims of the ’354 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero’s Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 211186 shall be no earlier than the expiration of the ’354 patent and any additional periods of exclusivity.

104. On information and belief, Hetero knows, or should know, and intends that physicians will prescribe and patients will take Hetero’s Generic Product for which approval is sought in ANDA No. 211186, and therefore will infringe at least one claim in the ’354 patent.

105. On information and belief, Hetero had knowledge of the ’354 patent and, by its promotional activities and proposed package insert for Hetero’s Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the ’354 patent, either literally or under the doctrine of equivalents.

106. On information and belief, Hetero is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Hetero’s Generic Product according to the instructions in the proposed package insert in a way that directly infringes the ’354 patent.

107. The offering to sell, sale, making, and/or importation of Hetero’s Generic Product would actively induce infringement of at least one of the claims of the ’354 patent, either literally or under the doctrine of equivalents. Hetero has knowledge and is aware of Plaintiffs’ ’354 patent.

108. On information and belief, if ANDA No. 211186 is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero's Generic Product.

109. Hetero has had and continues to have knowledge that Hetero's Generic Product is especially adapted for a use that infringes the '354 patent.

110. On information and belief, Hetero has had and continues to have knowledge that there is no substantial non-infringing use for Hetero's Generic Product.

111. On information and belief, Hetero's actions relating to Hetero's ANDA No. 211186 complained of herein were done by and for the benefit of Hetero.

112. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing or actively inducing infringement of at least one claim of the '354 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT IV

(DECLARATORY JUDGEMENT OF INFRINGEMENT OF THE '354 PATENT)

113. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

114. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

115. There is an actual and justiciable controversy between Plaintiffs and Hetero concerning infringement of the '354 patent of sufficient immediacy and reality such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

116. Hetero has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Hetero's Generic Product prior to expiration of the '354 patent.

117. Hetero's actions, including, but not limited to, submitting, or causing to be submitted to the FDA, ANDA No. 211186 seeking approval to manufacture, use, import, offer to sell and sell Hetero's Generic Product before the expiration date of the '354 patent and engaging in litigation, indicate a refusal to change the course of their actions in the face of knowledge of the '354 patent and acts by Plaintiffs.

118. On information and belief, the FDA could approve Hetero's ANDA No. 211186 prior to expiration of the '354 patent and as early as the expiration of the '646 patent and conclusion of the First Suit, which is currently scheduled for trial in January 2021.

119. On information and belief, Hetero intends to manufacture, use, import, offer to sell and/or sell Hetero's Generic Product upon FDA approval of ANDA No. 211186.

120. Upon FDA approval of ANDA No. 211186, Hetero will infringe one or more claims of the '354 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Generic Product, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c).

121. On information and belief, Hetero knows, or should know, and intends that physicians will prescribe and patients will take Hetero's Generic Product for which approval is sought in ANDA No. 211186, and therefore will infringe at least one claim in the '354 patent.

122. On information and belief, Hetero had knowledge of the '354 patent and, by its promotional activities and proposed package insert for Hetero's Generic Product, knows or should

know that it will induce direct infringement of at least one of the claims of the ’354 patent, either literally or under the doctrine of equivalents.

123. On information and belief, Hetero is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Hetero’s Generic Product according to the instructions in the proposed package insert in a way that directly infringes the ’354 patent.

124. The offering to sell, sale, making, and/or importation of Hetero’s Generic Product would actively induce infringement of at least one of the claims of the ’354 patent, either literally or under the doctrine of equivalents. Hetero has knowledge and is aware of Plaintiffs’ ’354 patent.

125. On information and belief, if ANDA No. 211186 is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero’s Generic Product.

126. Hetero has had and continues to have knowledge that Hetero’s Generic Product is especially adapted for a use that infringes the ’354 patent.

127. On information and belief, Hetero has had and continues to have knowledge that there is no substantial non-infringing use for Hetero’s Generic Product.

128. On information and belief, Hetero’s actions relating to Hetero’s ANDA No. 211186 complained of herein were done by and for the benefit of Hetero.

129. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing or actively inducing infringement of at least one claim of the ’354 patent.

130. Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

131. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Hetero’s Generic Product prior to

expiration of the ’354 patent by Hetero will constitute direct infringement, contributory infringement and/or active inducement of infringement of the ’354 patent.

COUNT V

(INFRINGEMENT OF THE ’536 PATENT UNDER 35 U.S.C. § 271(e)(2))

132. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

133. On information and belief, Hetero filed ANDA No. 211186 in order to obtain approval to manufacture, use, import, offer to sell and/or sell Hetero’s Generic Product in the United States before the expiration of the ’536 patent.

134. On information and belief, in its ANDA No. 211186, Hetero has represented to the FDA that Hetero’s Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs’ APTIOM® tablets.

135. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211186 seeking approval for the commercial manufacture, use, or sale of Hetero’s Generic Product before the expiration date of the ’536 patent, constitutes infringement, either literally or under the doctrine of equivalents.

136. Upon FDA approval of ANDA No. 211186, Hetero will infringe one or more claims of the ’536 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero’s Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 211186 shall be no earlier than the expiration of the ’536 patent and any additional periods of exclusivity.

137. On information and belief, Hetero knows, or should know, and intends that physicians will prescribe and patients will take Hetero's Generic Product for which approval is sought in ANDA No. 211186, and therefore will infringe at least one claim in the '536 patent.

138. On information and belief, Hetero had knowledge of the '536 patent and, by its promotional activities and proposed package insert for Hetero's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '536 patent, either literally or under the doctrine of equivalents.

139. On information and belief, Hetero is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Hetero's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '536 patent.

140. The offering to sell, sale, making, and/or importation of Hetero's Generic Product would actively induce infringement of at least one of the claims of the '536 patent, either literally or under the doctrine of equivalents. Hetero has knowledge and is aware of Plaintiffs' '536 patent.

141. On information and belief, if ANDA No. 211186 is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero's Generic Product.

142. Hetero has had and continues to have knowledge that Hetero's Generic Product is especially adapted for a use that infringes the '536 patent.

143. On information and belief, Hetero has had and continues to have knowledge that there is no substantial non-infringing use for Hetero's Generic Product.

144. On information and belief, Hetero's actions relating to Hetero's ANDA No. 211186 complained of herein were done by and for the benefit of Hetero.

145. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing or actively inducing infringement of at least one claim of the ’536 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

COUNT VI

(DECLARATORY JUDGEMENT OF INFRINGEMENT OF THE ’536 PATENT)

146. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

147. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

148. There is an actual and justiciable controversy between Plaintiffs and Hetero concerning infringement of the ’536 patent of sufficient immediacy and reality such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

149. Hetero has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Hetero’s Generic Product prior to expiration of the ’536 patent.

150. Hetero’s actions, including, but not limited to, submitting, or causing to be submitted to the FDA, ANDA No. 211186 seeking approval to manufacture, use, import, offer to sell and sell Hetero’s Generic Product before the expiration date of the ’536 patent and engaging in litigation, indicate a refusal to change the course of their actions in the face of knowledge of the ’536 patent and acts by Plaintiffs.

151. On information and belief, the FDA could approve Hetero's ANDA No. 211186 prior to expiration of the '536 patent and as early as the expiration of the '646 patent and conclusion of the First Suit, which is currently scheduled for trial in January 2021.

152. On information and belief, Hetero intends to manufacture, use, import, offer to sell and/or sell Hetero's Generic Product upon FDA approval of ANDA No. 211186.

153. Upon FDA approval of ANDA No. 211186, Hetero will infringe one or more claims of the '536 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's Generic Product, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c).

154. On information and belief, Hetero knows, or should know, and intends that physicians will prescribe and patients will take Hetero's Generic Product for which approval is sought in ANDA No. 211186, and therefore will infringe at least one claim in the '536 patent.

155. On information and belief, Hetero had knowledge of the '536 patent and, by its promotional activities and proposed package insert for Hetero's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '536 patent, either literally or under the doctrine of equivalents.

156. On information and belief, Hetero is aware and/or has knowledge that it is advertising an infringing use and/or instructing how to engage in an infringing use because healthcare professionals and/or patients will use Hetero's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '536 patent.

157. The offering to sell, sale, making, and/or importation of Hetero's Generic Product would actively induce infringement of at least one of the claims of the '536 patent, either literally or under the doctrine of equivalents. Hetero has knowledge and is aware of Plaintiffs' '536 patent.

158. On information and belief, if ANDA No. 211186 is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero's Generic Product.

159. Hetero has had and continues to have knowledge that Hetero's Generic Product is especially adapted for a use that infringes the '536 patent.

160. On information and belief, Hetero has had and continues to have knowledge that there is no substantial non-infringing use for Hetero's Generic Product.

161. On information and belief, Hetero's actions relating to Hetero's ANDA No. 211186 complained of herein were done by and for the benefit of Hetero.

162. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing or actively inducing infringement of at least one claim of the '536 patent.

163. Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

164. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Hetero's Generic Product prior to expiration of the '536 patent by Hetero will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '536 patent.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Hetero has infringed at least one claim of the patents-in-suit through Hetero's submission of ANDA No. 211186 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero's Generic Product in the United States before the expiration of the patents-in-suit;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Hetero's making, using, offering to sell, selling or importing Hetero's Generic Product prior to the expiration of the patents-in-suit will infringe, actively induce infringement, and/or contribute to the infringement of the patents-in-suit under 35 U.S.C. § 271(a), (b) and/or (c);

C. The issuance of an order that the effective date of any FDA approval of Hetero's Generic Product shall be no earlier than the expiration date of the patents-in-suit and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and/or permanent injunction, enjoining Hetero and all persons acting in concert with Hetero from commercially manufacturing, using, offering for sale, or selling Hetero's Generic Product within the United States, or importing Hetero's Generic Product into the United States, until the expiration of the patents-in-suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining Hetero and all persons acting in concert with Hetero from seeking, obtaining or maintaining approval of the ANDA until the expiration of the patents-in-suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The issuance of a declaration and the entry of judgment under 28 U.S.C. §§ 2201 and 2202 that any future commercial manufacture, use, offer for sale, sale and/or importation of Hetero's Generic Product prior to expiration of the patents-in-suit by Hetero will constitute direct

infringement, contributory infringement and/or active inducement of infringement of the patents-in-suit under 35 U.S.C. §§ 271(a)-(c);

G. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

H. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

I. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

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