IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRECKENRIDGE PHARMACEUTICAL, INC.,	)	
Plaintiff,	)	C.A. No.
v.	)	**JURY TRIAL DEMANDED**
HETERO USA INC., HETERO LABS LIMITED UNIT-III, HETERO LABS LIMITED., and CAMBER PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiff Breckenridge Pharmaceutical, Inc. ("Breckenridge"), by and through its attorneys, for its Complaint against Defendants Hetero USA Inc., Hetero Labs Limited Unit - III, Hetero Labs Limited., and Camber Pharmaceuticals, Inc. (collectively "Hetero"), alleges as follows:

THE NATURE OF THE ACTION

1. This is a civil action for patent infringement under the laws of the United States, Title 35, United States Code § 100 *et. seq.,* including 35 U.S.C. §§ 271 and 281, of U.S. Patent Nos. 11,013,729 ("the '729 Patent") and 11,752,142 ("the '142 Patent") (collectively, the "Patents-in-Suit").

2. Breckenridge owns the Patents-in-Suit. The '729 Patent claims oral pharmaceutical compositions of dabigatran etexilate, and the '142 Patent claims methods for reducing the risk of stroke or systemic embolism and methods for treating venous thromboembic events by administering the claimed dabigatran compositions to patients.

3. Hetero is engaged in the manufacture, use, offer for sale, sale, and/or importation of dabigatran etexilate mesylate capsule products, one capsule product containing 75 mg of

dabigatran etexilate (NDC31722-621-60), and another capsule product containing 150 mg of dabigatran etexilate (NDC31722-622-60) ("Hetero's Dabigatran Products"). Both of Hetero's Dabigatran Products and the method of use of same fall within the scope of one or more claims of the Patents-in-Suit.

4. Hetero directly infringes one or more claims of the '729 Patent.

5. Hetero actively induces, and contributes to, the direct infringement of the '142 Patent by others.

PARTIES

6. Breckenridge is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 200 Connell Drive, Suite 4200, Berkeley Heights, New Jersey 07922.

7. 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. Hetero USA, Inc. is the United States Regulatory Agent for Hetero Labs Limited Unit - III, a division of Hetero Labs Limited.

8. 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.

9. Hetero Unit - III is a division of Hetero Labs Limited. Hetero Unit - III itself and through its affiliates and subsidiaries, including Hetero USA, Inc., Camber Pharmaceuticals, Inc., and Hetero Labs Limited, formulates, manufactures, packages, and markets pharmaceutical products, including Hetero's Dabigatran Products, for distribution in the District of Delaware and throughout the United States.

10. 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. Hetero Labs is the parent company of Hetero USA, Inc. and Hetero Unit - III.

11. Hetero Labs itself and through its affiliates and subsidiaries, including Hetero USA, Camber Pharmaceuticals, Inc., and Hetero Unit - III, formulates, manufactures, packages, and markets pharmaceutical products, including Hetero's Dabigatran Products, for distribution in the District of Delaware and throughout the United States.

12. Hetero USA Inc. is in the business of, among other things, developing, manufacturing, and selling pharmaceutical products, including Hetero's Dabigatran Products, in the United States market, including in the District of Delaware.

13. Camber Pharmaceuticals, Inc. ("Camber") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business in Piscataway, NJ.

14. Camber is in the business of, among other things, manufacturing and distributing pharmaceutical products, also specifically including Hetero's Dabigatran Products, in the United States market, including in the District of Delaware.

15. Hetero USA Inc., Hetero Labs, Hetero Unit – III, and Camber collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products, including Hetero's Dabigatran Products, in the United States market including in the District of Delaware.

16. Hetero USA Inc., Hetero Labs, Hetero Unit – III, and Camber are agents of each other and/or operate in concert as integrated parts of the same business group.

JURISDICTION AND VENUE

17. This action arises under the patent laws of the United States of America, 35 U.S.C. § 100, *et seq*.

18. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338(a) in that this is a civil action arising out of the patent laws of the United States of America.

19. This Court has personal jurisdiction over Hetero on the basis that Hetero collectively has had persistent and continuous contacts with Delaware.

20. Hetero has purposefully and repeatedly availed itself of the benefits and protections of Delaware's laws, such that it should reasonably anticipate being haled into court here.

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

22. Camber is a corporation formed under the laws of the State of Delaware and is registered to do business in Delaware.

23. Hetero Labs and Hetero Unit – III direct the actions of Hetero, Camber, and Hetero USA, Inc. in Delaware.

24. Hetero regularly and continuously transacts business in Delaware, including by selling pharmaceutical products, including Hetero's Dabigatran Products, in Delaware.

25. Hetero derives substantial revenue from the sale of Hetero's Dabigatran Products in Delaware and has availed itself of the privilege of conducting business within Delaware.

26. Hetero has, on several occasions, committed acts of infringement in this judicial district.

27. Hetero has, on several occasions, consented to personal jurisdiction of this Court.

28. Hetero has, on several occasions, consented to venue before this Court.

29. On the basis of all facts alleged in this Complaint, venue is proper in this Court under 28 U.S.C. § 1400(b).

PATENTS-IN-SUIT

30. The '729 Patent, entitled "Oral Pharmaceutical Compositions of Dabigatran Etexilate," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO") on May 25, 2021. A true and correct copy of the '729 Patent is attached hereto as Exhibit A.

31. Breckenridge is the owner of the '729 Patent.

32. The '729 Patent claims, among other things, a composition comprising a mixture of at least two distinct types of particles. The first type of particles comprises dabigatran etexilate and is free from organic and inorganic acids. The second type of particles comprise at least one pharmaceutically acceptable organic acid, wherein the second type of particles is coated with a protective coating layer and is free from dabigatran etexilate.

33. The '142 Patent, entitled "Oral Pharmaceutical Compositions of Dabigatran Etexilate," was duly and lawfully issued by the USPTO on September 12, 2023. A true and correct copy of the '142 Patent is attached hereto as Exhibit B.

34. Breckenridge is the owner of the '142 Patent.

35. The '142 Patent claims, among other things, methods for reducing the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation and methods for treating venous thromboembolic events. Both methods require administering a composition comprising a mixture of at least two distinct types of particles, wherein the first type of particles comprise dabigatran etexilate and is free from organic and inorganic acids, and the second type of particles

comprise at least one pharmaceutically acceptable organic acid, wherein the second type of particles is coated with a protective coating layer and is free from dabigatran etexilate.

INFRINGEMENT BY HETERO

36. Hetero manufactures, uses, offers for sale, sells, and/or imports in the United States Hetero's Dabigatran Products.

37. Hetero's Dabigatran Products are AB rated generic drug products, approved by the FDA as bioequivalent to Pradaxa®, and they were (upon information and belief) first marketed in the United States by Hetero on or about early September of 2022.

38. Hetero's Dabigatran Products contain a first type of particles that comprise dabigatran etexilate mesylate and is free from organic and inorganic acids.

39. Hetero's Dabigatran Products contain a second type of particles that comprise tartaric acid (a pharmaceutically acceptable organic acid) and is free from dabigatran etexilate.

40. The second type of particles in Hetero's Dabigatran Products is coated with a protective coating.

41. Hetero's Dabigatran Products are marketed by Hetero in the United States as indicated: to reduce the risk of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation; for the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in adult patients who have been treated with a parenteral anticoagulant for 5 for 10 days; and to reduce the risk of recurrence of DVT and PE in adult patients who have been previously treated.

42. The development, marketing, and sale of Hetero's Dabigatran Products has been carried out in a manner that is not consistent with the standards of behavior in the United States pharmaceutical industry, which is to both rely upon and respect intellectual property rights.

43. On or about April 8, 2022, a Breckenridge executive sent a letter to Hetero's Vice President of Intellectual Property & Portfolio Management, informing Hetero of issuance of the '729 Patent, and inviting Hetero to discuss how the patent may be relevant to Hetero's Dabigatran Products.

44. On April 12, 2022, a Director of Intellectual Property at Hetero USA, Inc. responded to the April 8, 2022 letter, acknowledging its receipt, and stating that Hetero USA, Inc. respects "valid patents in every country concerned as a matter of our company policy and business ethics," and concluded that he would "look into this matter and respond . . . as appropriate."

45. To date, Hetero has not further responded to the Breckenridge letter of April 8, 2022.

46. On or about October 23, 2023, another Breckenridge executive sent a letter to Hetero's Vice President of Intellectual Property & Portfolio Management, again informing Hetero of the '729 Patent. The same letter also informed Hetero of the issuance of the '142 Patent, and invited Hetero to discuss how both patents may be relevant to Hetero's Dabigatran Products.

47. To date, Hetero has not responded to the Breckenridge letter of October 23, 2023.

48. Upon information and belief, Hetero has committed the acts of infringement as described in this Complaint in the absence of a good faith basis to reasonably believe its conduct is (or was) not an act of infringement of the Patents-in-Suit.

49. Upon information and belief, Hetero has committed the acts of infringement as described in this Complaint in the absence of a good faith belief that the Patents-in-Suit are invalid, or not enforceable.

50. Hetero has made no good faith effort to avoid infringing the Patents-in-Suit.

51. Hetero's past, present, and continued infringement of the Patents-in-Suit is willful.

CLAIMS FOR RELIEF

Count I – INFRINGEMENT OF THE '729 PATENT UNDER 35 U.S.C. § 271(a) and (g)

52. Breckenridge incorporates each of the preceding paragraphs 1-51 as fully set forth herein.

53. Hetero has used, imported, offered for sale, and sold in the United States Hetero's Dabigatran Products, and continues to use, import, offer for sale, and sell Hetero's Dabigatran Products in the United States, without authority or license from Breckenridge.

54. Hetero, without authority or license from Breckenridge, imports into the United States Hetero's Dabigatran Products, which are capsules that are made, upon information and belief, by a granulation process that is claimed by at least claim 8 of the '729 Patent.

55. The use, importation, offer for sale, and/or sale in the United States of Hetero's Dabigatran Products directly infringes at least claims 1, 8, 11, and 16 of the '729 Patent under 35 U.S.C. §§ 271(a) and (g).

56. Hetero had actual and constructive knowledge of the '729 Patent prior to and during its use, offer for sale, sale, and/or importation of Hetero's Dabigatran Products in the United States.

57. Hetero was, and continues to be, aware of the fact that its conduct constitutes an act of infringement of the '729 Patent.

58. Breckenridge has been damaged by Hetero's infringement of the '729 Patent in an amount to be proven at trial.

59. Breckenridge has been and will continue to be irreparably damaged in the future, unless Hetero is permanently enjoined from infringing the '729 Patent.

60. By reason of the Hetero's infringement, Breckenridge is entitled to recover its actual damages, including the costs of this litigation pursuant to 35 U.S.C. §§ 284, and to injunctive

relief pursuant to 35 U.S.C. § 283 to prevent further violation of the rights secured by Breckenridge by the '729 Patent.

Count II – INFRINGEMENT OF THE '142 PATENT UNDER 35 U.S.C. § 271(b) and (c)

61. Breckenridge incorporates each of the preceding paragraphs 1-60 as fully set forth herein.

62. Hetero has used, imported, offered for sale, and sold in the United States Hetero's Dabigatran Products, and continues to use, import, offer for sale, and sell Hetero's Dabigatran Products in the United States, without authority or license from Breckenridge.

63. Hetero's Dabigatran Products are sold in the United States with an accompanying FDA approved label, as well as an FDA approved Medication Guide, which instructs patients and physicians on the safe use of the Hetero Dabigatran Products.

64. Hetero's FDA approved label instructs that dabigatran etexilate capsules are a direct thrombin inhibitors indicated: to reduce the risk of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation; for the treatment of DVT and PE in adult patients who have been treated with a parenteral anticoagulant for 5 to 10 days; and to reduce the risk of recurrence of DVT and PE in adult patients who have been previously treated.

65. Hetero's FDA approved Medication Guide instructs patients and physicians that Hetero's Dabigatran Products, when administered orally, will reduce the risk of stroke and blood clots in adults who have a medical condition called atrial fibrillation that is not caused by a heart valve problem, which can lead to formation of blood clots and increase the risk of a stroke.

66. Hetero's FDA approved Medication Guide instructs patients and physicians that Hetero's Dabigatran Products, when administered orally, will treat blood clots in the veins of the

patient's legs (deep vein thrombosis) and lungs (pulmonary embolism) after the patient is treated with an injectable medicine to treat blood clots for 5 to 10 days.

67. Hetero's FDA approved Medication Guide instructs patients and physicians that Hetero's Dabigatran Products, when administered orally, will reduce the risk of blood clots from happening again in the veins of the patient's legs (deep vein thrombosis) and lungs (pulmonary embolism) after the patient received treatment for blood clots.

68. To support the use and sale of Hetero's Dabigatran Products in the United States, Hetero (through Camber's generic copay program) provides a coupon directly to patients and instructs those patients to obtain a valid prescription from a physician, fill that prescription by taking it to a participating pharmacy, and present the coupon for redemption at the pharmacy.

69. Upon information and belief, redemption of the coupon that is the subject of the preceding paragraph at the pharmacy allows the patient to receive a discount on the price of the Hetero Dabigatran Products assuming the patient qualifies under the terms of the generic copay program and encourages patients to request Hetero's Dabigatran Products for administration for the indications as recited in Hetero's FDA Approved Label.

70. Hetero intends that the Hetero Dabigatran Products will be prescribed by physicians as an AB rated generic substitution for use by patients to treat all conditions for which Pradaxa® may be used in the United States.

71. Physicians who prescribe Hetero's Dabigatran Products to patients are directing the administration of Hetero's Dabigatran Products in accordance with Hetero's FDA Approved Label and Medication Guide, and therefore infringe the '142 Patent when prescribing Hetero's Dabigatran Products.

72. Hetero knows and specifically intends that physicians instruct patients to administer Hetero's Dabigatran Products in a manner that infringes at least claims 1, 8 and 16 of the '142 Patent.

73. Hetero has sought and currently seeks to encourage the use, offer for sale, and/or sale of Hetero's Dabigatran Products while the '142 Patent is in force with the intent to cause the infringing use by physicians.

74. Hetero had actual and constructive knowledge of the '142 Patent prior to Hetero's use, importation, offer for sale, and/or sale in the United States of Hetero's Dabigatran Products and was aware that doing so constituted an act of infringement of the '142 Patent under 35 U.S.C. § 271(b) and (c).

75. The capsules within Hetero's Dabigatran Products are components of a product for use in practicing the methods of the '142 Patent and are not a staple article or commodity of commerce, suitable for substantial non-infringing use in the United States.

76. The capsules are a material part of the of the inventions claimed in the '142 Patent.

77. Hetero has been and is aware of the '142 patent and knows that the capsules within Hetero's Dabigtran Products are specially made or adapted for uses by physicians that infringe at least claims 1, 8 and 16 of the '142 Patent.

78. Physicians who direct the administration of Hetero's Dabigatran Products to patients directly infringe at least method claims 1, 8 and 16 of the '142 Patent.

79. Hetero had actual and constructive knowledge of the '142 Patent prior to the use, offer for sale, sale, and/or importation in the United States of Hetero's Dabigatran Products and was aware that doing so constituted an act of infringement of the '142 Patent.

80. The marketing, use, importation, offer for sale, and/or sale in the United States of Hetero's Dabigatran Products with Hetero's FDA Approved Label and Medication Guide indirectly infringes at least one claim of the '142 Patent under 35 U.S.C. §§ 271(b) and (c).

81. Breckenridge has been damaged by Hetero's infringement of the '142 Patent in an amount to be proven at trial.

82. Breckenrdidge has been and will continue to be irreparably damaged in the future unless Hetero is permanently enjoined from infringing the '142 Patent.

83. By reason of the Hetero's infringement, Plaintiff is entitled to recover its actual damages, the costs of this litigation pursuant to 35 U.S.C. §§ 284, and injunctive relief pursuant to 35 U.S.C. § 283 to prevent further violation of the rights secured by Breckenridge by the '142 Patent.

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38, Breckenridge respectfully demands a trial by jury on all issues properly triable by a jury in this action.

PRAYER FOR RELIEF

On motion or after a trial by jury, Breckenridge asks that the Court grant the following relief in its favor and against Hetero:

(a) Preliminarily and permanently enjoin Hetero, including of its officers, directors, principals, agents, servants, employees, successors, assigns, affiliates, and all that are in active concert or participation with Hetero from further infringement of each of the Patents-in-Suit pursuant to 25 U.S.C. § 283;

(b) Enter judgment that Hetero has infringed, and/or induced the infringement, of one or more claims of each of the Patents-in-Suit;

(c) Enter judgement finding Hetero's infringement to have been willful;

(d) Award Breckenridge damages adequate to compensate it for Hetero's infringement of each of the Patents-in-Suit, including lost profits, but in no event less than a reasonable royalty;

(e) Award Breckenridge up to three times actual damages for Hetero's willful infringement of each of the Patents-in-Suit pursuant to35 U.S.C. § 284;

(f) Award Breckenridge its attorneys' fees, costs, and expenses pursuant to 35 U.S.C. § 285 in the event that the Court finds Breckenridge to be the prevailing party, and Hetero's conduct to be exceptional; and

(g) Grant Breckenridge such further and other relief as the Court may deem just and proper.

/s/ Kelly E. Farnan

Kelly E. Farnan (#4395)
Sara M. Metzler (#6509)
Jessica E. Blau (#7163)
Richards, Layton & Finger, P.A.
One Rodney Square
920 North King Street
Wilmington, DE 19801
(302) 651-7700
farnan@rlf.com
metzler@rlf.com
blau@rlf.com

Attorneys for Plaintiff Breckenridge Pharmaceutical, Inc.

OF COUNSEL:

Christopher J. Sorenson
W. Reid Morris
MERCHANT & GOULD PC
150 South Fifth St., Suite 2200
Minneapolis, MN 55402
(612) 332-5300
csorenson@merchantgould.com
wrmorris@merchantgould.com

Jason M. Wiener
MERCHANT & GOULD PC
1900 Duke Street, Suite 600
Alexandria, VA 22314
(703) 684-2500
jwiener@merchantgould.com

Dated: May 10, 2024