IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. Plaintiff, v. HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, and HETERO USA INC., Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff AbbVie Inc. ("AbbVie" or "Plaintiff"), by its attorneys, brings this action against Defendants Hetero Labs Limited ("Hetero Labs"), Hetero Labs Limited Unit-V ("Hetero Unit-V"), and Hetero USA Inc. ("Hetero USA") (collectively, "Hetero"), and alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 11,690,845 ("the '845 patent") and 11,690,854 ("the '854 patent") 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 Hetero's recent submission to the United States Food and Drug Administration ("FDA") of an Abbreviated New Drug Application ("ANDA") seeking approval to market generic versions of Plaintiff's commercial pharmaceutical product ORILISSA® (elagolix sodium oral tablets, (eq. 150 mg base and eq. 200 mg base), submitted under New Drug Application ("NDA") No. 210450), prior to the expiration of patents listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for ORILISSA®. Hetero has submitted ANDA No. 217690 ("Hetero's ANDA"), which seeks approval

to market its generic version of ORILISSA®, elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base) ("Hetero's Generic Product"), prior to the expiration of the '845 and '854 patents.

2. Hetero has infringed one or more claims of the '845 and '854 patents under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 217690 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Hetero's Generic Product prior to the expiration of the '845 and '854 patents, or any extensions thereof. Hetero will infringe one or more claims of the '845 and '854 patents under 35 U.S.C. § 271(a), (b), and/or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Hetero's Generic Product prior to the expiration of the '845 and '854 patents, or any extensions thereof.

3. Plaintiff AbbVie Inc., along with AbbVie Ltd and Neurocrine Biosciences, Inc., previously filed a separate action in this Court against Hetero for patent infringement relating to ANDA No. 217690, which included counts for infringement of U.S. Patent Nos. 7,056,927 ("the '927 patent"), 7,419,983 ("the '983 patent"), 10,537,572 ("the '572 patent"), 10,682,351 ("the '351 patent"), and 11,344,551 ("the '551 patent"). *AbbVie Inc., et al. v. Alkem Laboratories Limited, et al.*, C.A. No. 22-1423-JLH (the "First Suit") was filed on October 27, 2022. The First Suit was filed in response to a letter from Hetero dated September 12, 2022 ("Hetero's First Notice Letter"), purporting to be "Notice of Certification Under 21 U.S.C. § 355(j)(2)(B)(ii)" for ANDA No. 217690 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 '927 patent, the '983 patent, the '572 patent, the '351 patent, and the '551 patent.

4. Plaintiff AbbVie Inc. also filed a separate action in this Court against Hetero for patent infringement relating to ANDA No. 217690, which included counts for infringement of

U.S. Patent No. 11,542,239 ("the '239 patent"). *AbbVie Inc. v. Hetero Labs Limited et al.*, C.A. No. 23-00448-JLH (the "Second Suit") was filed on April 24, 2023. The Second Suit was filed in response to a letter from Hetero dated March 10, 2023 ("Hetero's Second Notice Letter"), purporting to be a "Notice of Certification Under 21 U.S.C. § 355(j)(2)(B)(ii)" for ANDA No. 217690 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 '239 patent. The Second Suit was consolidated with the First Suit on August 16, 2023. *See AbbVie Inc. v. Hetero Labs Limited et al.*, C.A. No. 23-00448-JLH, D.I. 13.

5. Based on information and belief, Hetero is maintaining its certification as to the '927 patent, the '983 patent, the '572 patent, the '351 patent, the '551 patent, and the '239 patent set out in Hetero's First and Second Notice Letters. Thus, Plaintiffs will continue to prosecute all infringement counts presented in the First and Second Suits.

ORILISSA®

6. ORILISSA® is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis. Over 80,000 women have been prescribed ORILISSA®.

7. Endometriosis occurs when tissue that normally lines the inside of the uterus grows outside of the uterus (where it does not belong). These growths are referred to as lesions. During the menstrual cycle, estrogen levels rise and can cause endometriosis lesions to grow. Then, during a period, the lesions can break down and shred, causing pain throughout the month.

8. One way to manage common symptoms of endometriosis is to reduce the amount of estrogen the body produces. ORILISSA® inhibits endogenous GnRH signaling by binding competitive to GnRH receptors in the pituitary gland. ORILISSA® dials down estrogen, which can help manage endometriosis pain.

9. ORILISSA® was approved by the FDA on July 23, 2018, pursuant to NDA No. 210450. There are 2 different FDA approved dosage forms of ORILISSA®: 150 mg (administered orally once a day for management of moderate to severe pain associated with endometriosis) or 200 mg (administered orally twice a day for management of moderate to severe pain associated with endometriosis).

10. ORILISSA® is marketed and sold in the United States by AbbVie.

11. The '845 and '854 patents are listed in the Orange Book for ORILISSA®.

THE PARTIES

12. Plaintiff AbbVie is a corporation organized and existing under the laws of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is the assignee and owner of the '845 and '854 patents. AbbVie holds NDA No. 210450 for ORILISSA®. AbbVie is a global research and development-based biopharmaceutical company committed to developing innovative therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people, and unique approach to innovation to markedly improve treatments across therapeutic areas, including women's health.

13. AbbVie markets, distributes, and sells therapeutic drug products, including ORILISSA®, in this judicial district and throughout the United States.

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

15. 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.

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

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

18. On information and belief, Hetero USA is the Regulatory Agent for Hetero Labs and Hetero Unit-V.

19. On information and belief, each Hetero Labs, Hetero Unit-V, and 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, either individually or in concert.

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

21. On information and belief, Hetero Labs, Hetero Unit-V, and Hetero USA caused Hetero's ANDA to be submitted to FDA and seek FDA approval of Hetero's ANDA.

22. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of Hetero's ANDA, Hetero Labs, Hetero Unit-V, and Hetero USA will act in concert to distribute and sell the proposed generic elagolix sodium oral tablet (eq. 150 mg base and eq. 200 mg base) products described in Hetero's ANDA throughout the United States, including the State of Delaware.

JURISDICTION AND VENUE

23. Plaintiff incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

24. This action arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including 35 U.S.C. § 271.

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

26. This Court has personal jurisdiction over Defendants Hetero Labs, Hetero Unit-V, and Hetero USA because, on information and belief, each of Hetero Labs, Hetero Unit-V, and Hetero USA, *inter alia*, has continuous and systematic contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its affiliates, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell Hetero's Generic Product in the State of Delaware upon approval of ANDA No. 217690.

27. This Court has personal jurisdiction over Hetero Labs. On information and belief, Hetero Labs "is a research based global pharmaceutical company focused on development, manufacturing and marketing of Active Pharmaceutical Ingredients (APIs), Intermediate Chemicals & Finished Dosages." (https://www.indiamart.com/heterolabs-limited/aboutus.html, accessed Jan. 25, 2024). On information and belief, Hetero Labs directly, or indirectly, develops, manufactures, markets, imports, distributes, and sells pharmaceutical products, including generic drugs throughout the United States and in this judicial district. On information and belief, Hetero Labs purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

28. This Court has personal jurisdiction over Hetero Unit-V. On information and belief, Hetero Unit-V is the drug manufacturing facility for Hetero Labs and manufactures Hetero's generic products. (*See* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hetero-labs-limited-unit-v-520359-08152017, FDA Warning Letter, accessed Jan. 25, 2024). On information and belief, Hetero Unit-V directly, or indirectly, develops, manufactures, markets, imports, distributes, and sells pharmaceutical products, including generic drugs throughout the United States and in this judicial district. On information and belief, Hetero Unit-V purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

29. This Court has personal jurisdiction over Hetero USA because, *inter alia*, on information and belief, Hetero USA is a corporation organized and existing under the laws of the State of Delaware.

30. On 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, Delaware 19901.

31. On information and belief, Hetero USA "is the sales and marketing arm of Hetero's Active Pharmaceutical Ingredients (API) and Custom Pharmaceutical Services (CPS) business in USA." (https://www.hetero.com/presence, accessed Jan. 25, 2024). On information and belief, Hetero USA directly, or indirectly, develops, manufactures, markets, imports, distributes, and sells pharmaceutical products, including generic drugs throughout the United States and in this judicial district. On information and belief, Hetero USA purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

32. On information and belief, Hetero Labs, Hetero Unit-V, and Hetero USA, each directly or indirectly, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. On information and belief, Hetero Labs, Hetero Unit-V, and Hetero USA, each 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.

33. 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.

34. This Court also has personal jurisdiction over Hetero Labs, Hetero Unit-V, and Hetero USA 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").

35. This Court also has personal jurisdiction over Hetero Labs, Hetero Unit-V, and Hetero USA by virtue of the fact that, *inter alia*, each 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 Plaintiff in this District.

36. On information and belief, the effort to seek approval for ANDA No. 217690 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.

37. On information and belief, Hetero Labs is the holder of FDA Drug Master File No. 37037 for elagolix sodium.

38. On 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. 217690 and in commercializing Hetero's Generic Product in the United States, including in this judicial district, in accordance with ANDA No. 217690 upon approval. Through at least these activities, Hetero Labs, Hetero Unit-V, and Hetero USA have purposely availed themselves of the rights and benefits of Delaware law such that they should reasonably anticipate being haled into court in this judicial district.

39. On information and belief, Hetero Labs, Hetero Unit-V, and Hetero USA have been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of ANDA No. 217690 with Paragraph IV certifications regarding the '927, '983, '572, '351, '551, and '239 patents. On information and belief and as indicated by the First and Second Notice Letters, sent by Hetero to Plaintiff pursuant to 21 U.S.C. § 355(j)(2)(B), Hetero prepared and filed its ANDA with the intention of seeking to market Hetero's Generic Product nationwide, including within this judicial district.

40. On information and belief, and consistent with its practice with respect to other generic products, following FDA approval of ANDA No. 217690, Hetero will act in concert to import, market, distribute, offer for sale, and/or sell Hetero's Generic Product described in ANDA No. 217690 throughout the United States, including in Delaware and will derive substantial revenue from the use or consumption of Hetero's Generic Product in the state of Delaware.

41. On information and belief, if ANDA No. 217690 is approved, Hetero's Generic Product will be marketed, distributed, offered for sale, and/or sold in Delaware; prescribed by healthcare providers practicing in Delaware; administered by healthcare providers located within Delaware; and/or used by patients in Delaware, all of which will have a substantial effect on Delaware.

42. If ANDA No. 217690 is approved, Plaintiff will be harmed by the marketing, distribution, offer for sale, and/or sale of Hetero's Generic Product, including in Delaware.

43. 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. In particular, Hetero has been sued multiple times in this District without challenging personal jurisdiction and Hetero has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this District. *See, e.g.*, *AbbVie Inc. v. Alkem Labs. Ltd.*, C.A. No. 22-1423-JLH; *Novartis Pharms. Corp. v. Alkem Labs. Ltd.*, C.A. No. 21-1330-LPS; *Duchesnay, Inc. v. Hetero Labs. Ltd.*, C.A. No. 21-1130-LPS; *Novartis Pharms. Corp. v. Dr. Reddy's Labs., Inc.*, C.A. No. 19-2053-LPS; *Genentech, Inc. v. Hetero Labs Ltd.*, C.A. No. 19-178-RGA; *Biogen Int'l GmbH v. Amneal Pharms. LLC*, C.A. No. 17-823-LPS; *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, C.A. No. 18-1043-LPS.

44. Alternatively, this Court has personal jurisdiction over Hetero Labs pursuant to Fed. R. Civ. P. 4(k)(2), to the extent it is not subject to personal jurisdiction in the courts of any state, because Hetero Labs is a foreign entity organized under the laws of India, Plaintiff's claims arise under federal patent law, and the exercise of jurisdiction satisfies due process requirements, at least because, upon information and belief, Hetero Labs has systematic and continuous contacts throughout the United States by manufacturing, importing, marketing, and/or distributing

pharmaceutical products, including generic drug products, either by itself or through its parent corporation, subsidiaries and/or affiliates.

45. This Court also has personal jurisdiction over Hetero Unit-V pursuant to Fed. R. Civ. P. 4(k)(2), to the extent it is not subject to personal jurisdiction in the courts of any state, because Hetero Unit-V is a foreign entity organized under the laws of India, Plaintiff's claims arise under federal patent law, and the exercise of jurisdiction satisfies due process requirements, at least because, upon information and belief, Hetero Unit-V has systematic and continuous contacts throughout the United States by manufacturing, importing, marketing, and/or distributing pharmaceutical products, including generic drug products, either by itself or through its parent corporation, subsidiaries and/or affiliates.

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

47. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Hetero USA is incorporated in the State of Delaware.

48. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Hetero Labs is incorporated in India and may be sued in any judicial district in the United States.

49. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Hetero Unit-V is a division of Hetero Labs, which is incorporated in India and may be sued in any judicial district in the United States.

FACTUAL BACKGROUND

The NDA

50. AbbVie is the holder of NDA No. 210450 for ORILISSA® (elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base)) Tablets.

51. The FDA approved NDA No. 210450 on July 23, 2018, for management of moderate to severe pain associated with endometriosis.

52. ORILISSA® Tablets are prescription drugs approved for the management of moderate to severe pain associated with endometriosis. Elagolix sodium is the active ingredient in the ORILISSA® Tablets.

The Asserted Patents

53. The ’845 patent, titled “Methods of Administering Elagolix,” was duly and legally issued by the United States Patent and Trademark Office on July 4, 2023. A true and correct copy of the ’845 patent is attached as Exhibit A.

54. AbbVie owns the rights to the ’845 patent. The ’845 patent will expire on August 27, 2040.

55. The ’845 patent is listed in the FDA Orange Book in connection with NDA No. 210450 for ORILISSA® (elagolix sodium oral tablets (eq. 150 mg base and eq. 200 mg base)) Tablets.

56. The ’854 patent, titled “Methods of Treating Heavy Menstrual Bleeding,” was duly and legally issued by the United States Patent and Trademark Office on July 4, 2023. A true and correct copy of the ’854 patent is attached as Exhibit B.

57. AbbVie owns the rights to the ’854 patent. The ’854 patent will expire on April 19, 2038.

58. The ’854 patent is listed in the FDA Orange Book in connection with NDA No. 210450 for ORILISSA® (elagolix sodium oral tablets (eq. 150 mg base)) Tablets.

Hetero’s ANDA No. 217690

59. On information and belief, Hetero filed ANDA No. 217690 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of elagolix sodium oral tablets in eq. 150 mg base and eq. 200 mg base dosage forms, which are generic versions of Plaintiff’s ORILISSA® (elagolix sodium) Tablets.

60. ANDA No. 217690 contains Paragraph IV certifications, alleging that the claims of the ’927 patent, ’983 patent, ’572 patent, ’351 patent, ’551 patent, and ’239 patent are invalid, unenforceable, and/or would not be infringed by Hetero’s Generic Product.

61. The ’845 and ’854 patents had not issued at the time Hetero submitted its certifications under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act.

62. Hetero has knowledge and is aware of the ’845 and ’854 patents, including through at least its listing in the Orange Book with reference to ORILISSA® (elagolix sodium) Tablets.

63. On information and belief, following FDA approval of Hetero’s ANDA No. 217690, 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 ’845 and ’854 patents expire.

COUNT I
INFRINGEMENT OF THE ’845 PATENT BY HETERO UNDER § 271(e)(2)(A)

64. Plaintiff incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

65. Hetero's submission of ANDA No. 217690 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic elagolix sodium product(s) prior to the expiration of the '845 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A). On information and belief, the product described in ANDA No. 217690 would infringe, either literally or under the doctrine of equivalents, at least one claim of the '845 patent under 35 U.S.C. § 271(e)(2)(A).

66. On information and belief, in Hetero's ANDA, Hetero has represented to the FDA that Hetero's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiff's ORILISSA®.

67. On information and belief, Hetero filed Hetero's ANDA 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 '845 patent.

68. On information and belief, Hetero's generic elagolix sodium product(s) will, if approved and marketed, infringe at least one claim of the '845 patent.

69. On information and belief, upon FDA approval of Hetero's ANDA No. 217690, Hetero will further infringe, literally or under the doctrine of equivalents, at least one claim of the '845 patent directly under 35 U.S.C. § 271(a) and by inducement under 35 U.S.C. § 271(b) by making, using, offering to sell, marketing, and/or selling its generic elagolix sodium product(s) in the United States, unless enjoined by the Court.

70. On information and belief, Hetero knows, or should know, and intends that healthcare providers will prescribe and patients will take Hetero's Generic Product for which approval is sought in Hetero's ANDA, and therefore will infringe at least one claim in the '845 patent.

71. On information and belief, Hetero had knowledge of the '845 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 '845 patent, either literally or under the doctrine of equivalents.

72. 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 '845 patent.

73. On information and belief, if Hetero's ANDA is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero's Generic Product.

74. On information and belief, Hetero's actions relating to Hetero's ANDA complained of herein were done by and for the benefit of Hetero.

75. If Hetero's marketing and sale of generic elagolix sodium product(s) prior to expiration of the '845 patent and all other relevant exclusivities is not enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no remedy at law. Pursuant to 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '845 PATENT BY HETERO

76. Plaintiff incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

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

78. There is an actual and justiciable controversy between Plaintiff and Hetero concerning infringement of the '845 patent of sufficient immediacy and reality such that the Court

may entertain Plaintiff's 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.

79. On information and belief, 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 '845 patent, including Hetero's filing of ANDA No. 217690.

80. Hetero's actions, including, but not limited to, submitting, or causing to be submitted to the FDA, ANDA No. 217690 seeking approval to manufacture, use, import, offer to sell and sell Hetero's Generic Product before the expiration date of the '845 patent and engaging in litigation, indicate a refusal to change the course of their actions in the face of knowledge of the '845 patent and acts by Plaintiff.

81. On information and belief, Hetero intends to manufacture, use, import, offer to sell and/or sell Hetero's Generic Product after FDA approval of ANDA No. 217690.

82. After FDA approval of ANDA No. 217690, Hetero will infringe one or more claims of the '845 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).

83. On information and belief, if ANDA No. 217690 is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero's Generic Product.

84. On information and belief, Hetero's actions relating to Hetero's ANDA No. 217690 complained of herein were done by and for the benefit of Hetero.

85. Plaintiff will be irreparably harmed if Hetero is not enjoined from infringing or actively inducing infringement of at least one claim of the '845 patent.

86. Plaintiff is entitled to a permanent injunction against further infringement. Plaintiff do not have an adequate remedy at law.

87. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Hetero's Generic Product prior to the expiration of the '845 patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '845 patent.

COUNT III
INFRINGEMENT OF THE '854 PATENT BY HETERO UNDER § 271(e)(2)(A)

88. Plaintiff incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

89. Hetero's submission of ANDA No. 217690 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic elagolix sodium product(s) prior to the expiration of the '854 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A). On information and belief, the product described in ANDA No. 217690 would infringe, either literally or under the doctrine of equivalents, at least one claim of the '854 patent under 35 U.S.C. § 271(e)(2)(A).

90. On information and belief, in Hetero's ANDA, Hetero has represented to the FDA that Hetero's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiff's ORILISSA®.

91. On information and belief, Hetero filed Hetero's ANDA 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 '854 patent.

92. On information and belief, Hetero's generic elagolix sodium product(s) will, if approved and marketed, infringe at least one claim of the '854 patent.

93. On information and belief, upon FDA approval of Hetero's ANDA No. 217690, Hetero will further infringe, literally or under the doctrine of equivalents, at least one claim of the '854 patent directly under 35 U.S.C. § 271(a), by inducement under 35 U.S.C. § 271(b), and/or contributorily under 35 U.S.C. § 271(c) by making, using, offering to sell, marketing, and/or selling its generic elagolix sodium product(s) in the United States, unless enjoined by the Court.

94. On information and belief, Hetero knows, or should know, and intends that healthcare providers will prescribe and patients will take Hetero's Generic Product for which approval is sought in Hetero's ANDA, and therefore will infringe at least one claim in the '854 patent.

95. On information and belief, Hetero had knowledge of the '854 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 '854 patent, either literally or under the doctrine of equivalents.

96. 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 '854 patent.

97. On information and belief, if Hetero's ANDA is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero's Generic Product.

98. Hetero has had and continues to have knowledge that Hetero's Generic Product is especially adapted for a use that infringes the '854 patent.

99. 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.

100. On information and belief, Hetero's actions relating to Hetero's ANDA complained of herein were done by and for the benefit of Hetero.

101. If Hetero's marketing and sale of generic elagolix sodium product(s) prior to expiration of the '854 patent and all other relevant exclusivities is not enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no remedy at law. Pursuant to 35 U.S.C. § 283, Plaintiff is entitled to a permanent injunction against further infringement.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '854 PATENT BY HETERO

102. Plaintiff incorporates by reference the prior paragraphs of this Complaint as if fully set forth herein.

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

104. There is an actual and justiciable controversy between Plaintiff and Hetero concerning infringement of the '854 patent of sufficient immediacy and reality such that the Court may entertain Plaintiff's 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.

105. On information and belief, 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 '854 patent, including Hetero's filing of ANDA No. 217690.

106. Hetero's actions, including, but not limited to, submitting, or causing to be submitted to the FDA, ANDA No. 217690 seeking approval to manufacture, use, import, offer to sell and sell Hetero's Generic Product before the expiration date of the '854 patent and engaging

in litigation, indicate a refusal to change the course of their actions in the face of knowledge of the '854 patent and acts by Plaintiff.

107. On information and belief, Hetero intends to manufacture, use, import, offer to sell and/or sell Hetero's Generic Product after FDA approval of ANDA No. 217690.

108. After FDA approval of ANDA No. 217690, Hetero will infringe one or more claims of the '854 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).

109. On information and belief, if ANDA No. 217690 is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero's Generic Product.

110. Hetero has had and continues to have knowledge that Hetero's Generic Product is especially adapted for a use that infringes the '854 patent.

111. 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.

112. On information and belief, Hetero's actions relating to Hetero's ANDA No. 217690 complained of herein were done by and for the benefit of Hetero.

113. Plaintiff will be irreparably harmed if Hetero is not enjoined from infringing or actively inducing infringement of at least one claim of the '854 patent.

114. Plaintiff is entitled to a permanent injunction against further infringement. Plaintiff do not have an adequate remedy at law.

115. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Hetero's Generic Product prior to the expiration of

the ’854 patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the ’854 patent.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully requests 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 ’845 and ’854 patents through Hetero’s submission of ANDA No. 217690 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 ’845 and ’854 patents;

B. The entry of judgment that Hetero’s making, using, offering to sell, selling, or importing Hetero’s Generic Product prior to the expiration of the ’845 and ’854 patents will infringe, actively induce infringement, and/or contribute to the infringement of the ’845 and ’854 patents under 35 U.S.C. § 271(a), (b), and/or (c);

C. A declaration under 28 U.S.C. § 2201 that if Hetero, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Hetero’s Generic Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

D. 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 ’845 and ’854 patents and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

E. The entry of a 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 '845 and '854 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The entry of a 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 '845 and '854 patents, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

G. The issuance of a declaration that this is an exceptional case and an award to Plaintiff of its 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 Plaintiff of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
jtigan@morrisnichols.com
mdellinger@morrisnichols.com

Attorneys for Plaintiff AbbVie Inc.

OF COUNSEL:

Jennifer H. Roscetti
Danielle A. Duszczyszyn
William B. Raich
Constance P. Lee
Ryan V. McDonnell
Reinaldo Franqui Machin
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4431
(202) 408-4000

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