IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP., *Plaintiff,* v. APOTEX INC., and APOTEX CORP., *Defendants.*	C.A. No. _____

COMPLAINT

Plaintiff Merck Sharp & Dohme Corp. ("Merck"), by its attorneys, for its Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of defendants' submission of Abbreviated New Drug Application ("ANDA") Nos. 202425, 202426, and 205369 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import versions of JANUVIA® (sitagliptin phosphate), JANUMET® (metformin hydrochloride; sitagliptin phosphate), and JANUMET XR® (metformin hydrochloride; sitagliptin phosphate extended release tablets) prior to the expiration of U.S. Patent No. 7,326,708 ("the '708 patent").

2. Apotex Inc. notified Merck by letters dated December 13, 2010, and December 14, 2010 ("Apotex's '425 Notice Letters") that it had submitted to the FDA ANDA No. 202425 ("Apotex's '425 ANDA"), seeking approval from the FDA to engage in the commercial

manufacture, use, offering for sale, sale, and/or importation of generic sitagliptin phosphate oral tablets ("Apotex's '425 ANDA Product") prior to the expiration of the '708 patent.

3. On information and belief, Apotex's '425 ANDA Product is a generic version of Merck's JANUVIA®

4. Apotex Inc. notified Merck by letters dated December 13, 2010, and December 14, 2010 ("Apotex's '426 Notice Letters") that it had submitted to the FDA ANDA No. 202426 ("Apotex's '426 ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of generic metformin hydrochloride and sitagliptin phosphate oral tablets ("Apotex's '426 ANDA Product") prior to the expiration of the '708 patent.

5. On information and belief, Apotex's '426 ANDA Product is a generic version of Merck's JANUMET®.

6. Apotex Inc. and Apotex Corp. notified Merck by letter dated December 17, 2013 ("Apotex's '369 Notice Letter") that it had submitted to the FDA ANDA No. 205369 ("Apotex's '369 ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of generic metformin hydrochloride and sitagliptin phosphate extended release oral tablets ("Apotex's '369 ANDA Product") prior to the expiration of the '708 patent.

7. On information and belief, Apotex's '369 ANDA Product is a generic version of Merck's JANUMET XR®.

8. Apotex's '425 Notice Letters, Apotex's '426 Notice Letters, and Apotex's '369 Notice Letter are collectively referred to herein as "Apotex's Notice Letters." Apotex's '425 ANDA, Apotex's '426 ANDA, and Apotex's '369 ANDA are collectively referred to herein as

"Apotex's ANDAs." Apotex's '425 ANDA Product, Apotex's '426 ANDA Product, and Apotex's '369 ANDA Product are collectively referred to herein as "Apotex's ANDA Products."

PARTIES

9. Plaintiff Merck is a corporation organized and existing under the laws of New Jersey, having its corporate offices and principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

10. Merck is the holder of New Drug Application ("NDA") No. 21995 for JANUVIA® (sitagliptin phosphate), which has been approved by the FDA.

11. Merck is the holder of NDA No. 22044 for JANUMET® (metformin hydrochloride; sitagliptin phosphate), which has been approved by the FDA.

12. Merck is the holder of NDA No. 202270 for JANUMET XR® (metformin hydrochloride; sitagliptin phosphate extended release tablets), which has been approved by the FDA.

13. On information and belief, defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having its corporate offices and principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. On information and belief, Apotex Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Apotex Corp.

14. On information and belief, defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. On information and belief, Apotex Corp. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

15. On information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Inc. Apotex Inc. and Apotex Corp. are collectively referred to herein as "Apotex."

16. On information and belief, Apotex Inc. and Apotex Corp. acted in concert to prepare and submit Apotex's ANDAs to the FDA.

17. On information and belief Apotex Inc. and Apotex Corp. know and intend that upon approval of Apotex's ANDAs, Apotex Inc. and Apotex Corp. will manufacture, market, sell, and distribute Apotex's ANDA Products throughout the United States, including in Delaware. On information and belief, Apotex Inc. and Apotex Corp. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Apotex's ANDA Products, and enter into agreements that are nearer than arm's length. On information and belief, Apotex Inc. and Apotex Corp. participated, assisted, and cooperated in carrying out the acts complained of herein.

18. On information and belief, following any FDA approval of Apotex's ANDAs, Apotex Inc. and Apotex Corp. will act in concert to distribute and sell Apotex's ANDA Products throughout the United States, including within Delaware.

JURISDICTION

19. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

20. This Court has personal jurisdiction over Apotex.

21. Apotex Inc. is subject to personal jurisdiction in Delaware because, among other things, Apotex Inc., itself and through its wholly owned subsidiary Apotex Corp., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Apotex Inc., itself and through its wholly owned subsidiary Apotex Corp., develops, manufactures, imports,

markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Apotex Inc. is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Apotex Corp., and therefore the activities of Apotex Corp. in this jurisdiction are attributed to Apotex Inc.

22. Apotex Corp. is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Apotex Corp. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware related to Merck's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

23. In addition, this Court has personal jurisdiction over Apotex because Apotex Inc. and Apotex Corp. regularly engage in patent litigation concerning FDA-approved branded drug products in this district, do not contest personal jurisdiction in this district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Novartis Pharms. Corp. v. Apotex Inc.*, No. 18-1038-LPS, D.I. 9 (D. Del. Aug. 8, 2018); *Vanda Pharms. Inc. v. Apotex Inc.*, No. 18-689-CFC, D.I. 15 (D. Del. July 13, 2018); *Bial-Portela & CA, S.A. v. Apotex Inc.*, No. 18-cv-382-CFC, D.I. 11 (D. Del.

May 31, 2018); *Onyx Therapeutics, Inc. v. Apotex Inc.*, No. 18-132-LPS, D.I. 10 (D. Del. Feb. 26, 2018).

24. On information and belief, if Apotex's ANDAs are approved, Apotex Inc. and Apotex Corp. will manufacture, market, sell, and/or distribute Apotex's ANDA Products within the United States, including in Delaware, consistent with Apotex's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Apotex regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. On information and belief, Apotex's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Apotex's ANDA Products will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of Merck's patent in the event that Apotex's ANDA Products are approved before the patent expires.

25. On information and belief, Apotex derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Apotex and/or for which Apotex Inc. and/or Apotex Corp. is/are the named applicant(s) on approved ANDAs. On information and belief, various products for which Apotex Inc. and/or Apotex Corp. is/are the named applicant(s) on approved ANDAs are available at retail pharmacies in Delaware.

VENUE

26. Merck incorporates each of the preceding paragraphs 1–25 as if fully set forth herein.

27. Venue is proper in this district as to Apotex Inc. under 28 U.S.C. § 1391 because Apotex Inc. is a corporation organized and existing under the laws of Canada and is subject to personal jurisdiction in this judicial district.

28. Venue is proper in this district as to Apotex Corp. under 28 U.S.C. § 1400(b) because Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

THE '708 PATENT

29. Merck incorporates each of the preceding paragraphs 1–28 as if fully set forth herein.

30. The inventors named on the '708 patent are Stephen Howard Cypes, Alex Minhua Chen, Russell R. Ferlita, Karl Hansen, Ivan Lee, Vicky K. Vydra, and Robert M. Wenslow, Jr.

31. The '708 patent, entitled "Phosphoric Acid Salt of a Dipeptidyl Peptidase-IV Inhibitor" (attached as Exhibit A), was duly and legally issued on February 5, 2008.

32. Merck is the owner and assignee of the '708 patent.

33. The '708 patent claims, *inter alia*, a dihydrogenphosphate salt of 4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine of structural formula I, or a hydrate thereof, as recited in claim 1 of the '708 patent.

34. JANUVIA®, as well as methods of using JANUVIA®, are covered by one or more claims of the '708 patent, including claim 1 of the '708 patent, and the '708 patent has been listed in connection with JANUVIA® in the FDA's Orange Book.

35. JANUMET®, as well as methods of using JANUMET®, are covered by one or more claims of the '708 patent, including claim 1 of the '708 patent, and the '708 patent has been listed in connection with JANUMET® in the FDA's Orange Book.

36. JANUMET XR®, as well as methods of using JANUMET XR®, are covered by one or more claims of the ’708 patent, including claim 1 of the ’708 patent, and the ’708 patent has been listed in connection with JANUMET XR® in the FDA’s Orange Book.

COUNT I – INFRINGEMENT OF THE ’708 PATENT
(APOTEX’S ’425 ANDA PRODUCT)

37. Merck incorporates each of the preceding paragraphs 1–36 as if fully set forth herein.

38. In Apotex’s ’425 Notice Letters, Apotex notified Merck of the submission of Apotex’s ’425 ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Apotex’s ’425 ANDA Product prior to the expiration of the ’708 patent.

39. In Apotex’s ’425 Notice Letters, Apotex also notified Merck that, as part of its ANDA, Apotex had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to the ’708 patent. On information and belief, Apotex submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ’708 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Apotex’s ’425 ANDA Product.

40. In Apotex’s ’425 Notice Letters, Apotex stated that Apotex’s ’425 ANDA Product contains sitagliptin phosphate as an active ingredient.

41. Apotex’s ’425 ANDA Product, and the use of Apotex’s ’425 ANDA Product, are covered by one or more claims of the ’708 patent, including at least claim 1 of the ’708 patent, because claim 1 of the ’708 patent covers the sitagliptin phosphate contained in Apotex’s ’425 ANDA Product.

42. In Apotex's '425 Notice Letters, Apotex did not contest infringement of claim 1 of the '708 patent.

43. Apotex's submission of Apotex's '425 ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's '425 ANDA Product before the expiration of the '708 patent was an act of infringement of the '708 patent under 35 U.S.C. § 271(e)(2)(A).

44. On information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's '425 ANDA Product immediately and imminently upon approval of its ANDA.

45. The manufacture, use, sale, offer for sale, or importation of Apotex's '425 ANDA Product would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

46. On information and belief, the manufacture, use, sale, offer for sale, or importation of Apotex's '425 ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

47. On information and belief, Apotex plans and intends to, and will, actively induce infringement of the '708 patent when Apotex's '425 ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Apotex's activities will be done with knowledge of the '708 patent and specific intent to infringe that patent.

48. On information and belief, Apotex knows that Apotex's '425 ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '708 patent, that Apotex's '425 ANDA Product is not a staple article or commodity of commerce, and that

Apotex's '425 ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Apotex plans and intends to, and will, contribute to infringement of the '708 patent immediately and imminently upon approval of Apotex's '425 ANDA.

49. Notwithstanding Apotex's knowledge of the claims of the '708 patent, Apotex has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Apotex's '425 ANDA Product with its product labeling following FDA approval of Apotex's '425 ANDA prior to the expiration of the '708 patent.

50. The foregoing actions by Apotex constitute and/or will constitute infringement of the '708 patent; active inducement of infringement of the '708 patent; and contribution to the infringement by others of the '708 patent.

51. On information and belief, Apotex has acted with full knowledge of the '708 patent and without a reasonable basis for believing that it would not be liable for infringement of the '708 patent; active inducement of infringement of the '708 patent; and/or contribution to the infringement by others of the '708 patent.

52. Merck will be substantially and irreparably damaged by infringement of the '708 patent.

53. Unless Apotex is enjoined from infringing the '708 patent, actively inducing infringement of the '708 patent, and contributing to the infringement by others of the '708 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '708 PATENT (APOTEX'S '425 ANDA PRODUCT)

54. Merck incorporates each of the preceding paragraphs 1–53 as if fully set forth herein.

55. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Merck on the one hand and Apotex on the other regarding Apotex's infringement, active inducement of infringement, and contribution to the infringement by others of the '708 patent.

56. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Apotex's '425 ANDA Product with its proposed labeling, or any other Apotex drug product that is covered by or whose use is covered by the '708 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '708 patent, and that the claims of the '708 patent are valid.

COUNT III – INFRINGEMENT OF THE '708 PATENT
(APOTEX'S '426 ANDA PRODUCT)

57. Merck incorporates each of the preceding paragraphs 1–56 as if fully set forth herein.

58. In Apotex's '426 Notice Letters, Apotex notified Merck of the submission of Apotex's '426 ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Apotex's '426 ANDA Product prior to the expiration of the '708 patent.

59. In Apotex's '426 Notice Letters, Apotex also notified Merck that, as part of its ANDA, Apotex had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to the '708 patent. On information and belief, Apotex submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '708 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Apotex's '426 ANDA Product.

60. In Apotex's '426 Notice Letters, Apotex stated that Apotex's '426 ANDA Product contains sitagliptin phosphate as an active ingredient.

61. Apotex's '426 ANDA Product, and the use of Apotex's '426 ANDA Product, are covered by one or more claims of the '708 patent, including at least claim 1 of the '708 patent, because claim 1 of the '708 patent covers the sitagliptin phosphate contained in Apotex's '426 ANDA Product.

62. In Apotex's '426 Notice Letters, Apotex did not contest infringement of claim 1 of the '708 patent.

63. Apotex's submission of Apotex's '426 ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's '426 ANDA Product before the expiration of the '708 patent was an act of infringement of the '708 patent under 35 U.S.C. § 271(e)(2)(A).

64. On information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's '426 ANDA Product immediately and imminently upon approval of its ANDA.

65. The manufacture, use, sale, offer for sale, or importation of Apotex's '426 ANDA Product would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

66. On information and belief, the manufacture, use, sale, offer for sale, or importation of Apotex's '426 ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

67. On information and belief, Apotex plans and intends to, and will, actively induce infringement of the ’708 patent when Apotex’s ’426 ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Apotex’s activities will be done with knowledge of the ’708 patent and specific intent to infringe that patent.

68. On information and belief, Apotex knows that Apotex’s ’426 ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’708 patent, that Apotex’s ’426 ANDA Product is not a staple article or commodity of commerce, and that Apotex’s ’426 ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Apotex plans and intends to, and will, contribute to infringement of the ’708 patent immediately and imminently upon approval of Apotex’s ’426 ANDA.

69. Notwithstanding Apotex’s knowledge of the claims of the ’708 patent, Apotex has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Apotex’s ’426 ANDA Product with its product labeling following FDA approval of Apotex’s ’426 ANDA prior to the expiration of the ’708 patent.

70. The foregoing actions by Apotex constitute and/or will constitute infringement of the ’708 patent; active inducement of infringement of the ’708 patent; and contribution to the infringement by others of the ’708 patent.

71. On information and belief, Apotex has acted with full knowledge of the ’708 patent and without a reasonable basis for believing that it would not be liable for infringement of the ’708 patent; active inducement of infringement of the ’708 patent; and/or contribution to the infringement by others of the ’708 patent.

72. Merck will be substantially and irreparably damaged by infringement of the ’708 patent.

73. Unless Apotex is enjoined from infringing the ’708 patent, actively inducing infringement of the ’708 patent, and contributing to the infringement by others of the ’708 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’708 PATENT (APOTEX’S ’426 ANDA PRODUCT)

74. Merck incorporates each of the preceding paragraphs 1–73 as if fully set forth herein.

75. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Merck on the one hand and Apotex on the other regarding Apotex’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’708 patent.

76. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Apotex’s ’426 ANDA Product with its proposed labeling, or any other Apotex drug product that is covered by or whose use is covered by the ’708 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the ’708 patent, and that the claims of the ’708 patent are valid.

COUNT V – INFRINGEMENT OF THE ’708 PATENT (APOTEX’S ’369 ANDA PRODUCT)

77. Merck incorporates each of the preceding paragraphs 1–76 as if fully set forth herein.

78. In Apotex’s ’369 Notice Letter, Apotex notified Merck of the submission of Apotex’s ’369 ANDA to the FDA. The purpose of this submission was to obtain approval under

the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Apotex's '369 ANDA Product prior to the expiration of the '708 patent.

79. In Apotex's '369 Notice Letter, Apotex also notified Merck that, as part of its ANDA, Apotex had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to the '708 patent. On information and belief, Apotex submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '708 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Apotex's '369 ANDA Product.

80. In Apotex's '369 Notice Letter, Apotex stated that Apotex's '369 ANDA Product contains sitagliptin phosphate as an active ingredient.

81. Apotex's '369 ANDA Product, and the use of Apotex's '369 ANDA Product, are covered by one or more claims of the '708 patent, including at least claim 1 of the '708 patent, because claim 1 of the '708 patent covers the sitagliptin phosphate contained in Apotex's '369 ANDA Product.

82. In Apotex's '369 Notice Letter, Apotex did not contest infringement of claim 1 of the '708 patent.

83. Apotex's submission of Apotex's '369 ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's '369 ANDA Product before the expiration of the '708 patent was an act of infringement of the '708 patent under 35 U.S.C. § 271(e)(2)(A).

84. On information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's '369 ANDA Product immediately and imminently upon approval of its ANDA.

85. The manufacture, use, sale, offer for sale, or importation of Apotex's '369 ANDA Product would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

86. On information and belief, the manufacture, use, sale, offer for sale, or importation of Apotex's '369 ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

87. On information and belief, Apotex plans and intends to, and will, actively induce infringement of the '708 patent when Apotex's '369 ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Apotex's activities will be done with knowledge of the '708 patent and specific intent to infringe that patent.

88. On information and belief, Apotex knows that Apotex's '369 ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '708 patent, that Apotex's '369 ANDA Product is not a staple article or commodity of commerce, and that Apotex's '369 ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Apotex plans and intends to, and will, contribute to infringement of the '708 patent immediately and imminently upon approval of Apotex's '369 ANDA.

89. Notwithstanding Apotex's knowledge of the claims of the '708 patent, Apotex has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import

Apotex's '369 ANDA Product with its product labeling following FDA approval of Apotex's '369 ANDA prior to the expiration of the '708 patent.

90. The foregoing actions by Apotex constitute and/or will constitute infringement of the '708 patent; active inducement of infringement of the '708 patent; and contribution to the infringement by others of the '708 patent.

91. On information and belief, Apotex has acted with full knowledge of the '708 patent and without a reasonable basis for believing that it would not be liable for infringement of the '708 patent; active inducement of infringement of the '708 patent; and/or contribution to the infringement by others of the '708 patent.

92. Merck will be substantially and irreparably damaged by infringement of the '708 patent.

93. Unless Apotex is enjoined from infringing the '708 patent, actively inducing infringement of the '708 patent, and contributing to the infringement by others of the '708 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '708 PATENT (APOTEX'S '369 ANDA PRODUCT)

94. Merck incorporates each of the preceding paragraphs 1–93 as if fully set forth herein.

95. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Merck on the one hand and Apotex on the other regarding Apotex's infringement, active inducement of infringement, and contribution to the infringement by others of the '708 patent.

96. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Apotex's '369 ANDA Product with its proposed labeling, or any other

Apotex drug product that is covered by or whose use is covered by the ’708 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the ’708 patent, and that the claims of the ’708 patent are valid.

PRAYER FOR RELIEF

WHEREFORE, Merck requests the following relief:

(a) A judgment that the ’708 patent has been infringed under 35 U.S.C. § 271(e)(2) by Apotex’s submissions to the FDA of Apotex’s ANDAs;

(b) A judgment ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of Apotex’s ANDA Products, or any other drug product that infringes or the use of which infringes the ’708 patent, be not earlier than the latest of the expiration date of the ’708 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Apotex, and all persons acting in concert with Apotex, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Apotex’s ANDA Products, or any other drug product covered by or whose use is covered by the ’708 patent, prior to the expiration of the ’708 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Apotex’s ANDA Products, or any other drug product that is covered by or whose use is covered by the ’708 patent, prior to the expiration of the ’708 patent, will infringe, induce the infringement of, and contribute to the infringement by others of, the ’708 patent;

(e) A declaration that this is an exceptional case and an award of attorney’s fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

Dated: February 13, 2019

Respectfully submitted,

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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