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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ALKERMES, INC. and ALKERMES PHARMA IRELAND LIMITED, Plaintiffs, v. APOTEX CORP. and APOTEX INC., Defendants.	C.A. No. ____ (FILED ELECTRONICALLY)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Alkermes, Inc. and Alkermes Pharma Ireland Limited (together, "Alkermes" or "Plaintiffs"), by their undersigned attorneys, bring this action against Defendants Apotex Corp. and Apotex Inc. (together, "Apotex" or "Defendants"), and allege as follows:

PARTIES

1. Plaintiff Alkermes, Inc. is an entity organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 900 Winter Street, Waltham, Massachusetts 02451.

2. Alkermes, Inc. holds New Drug Application ("NDA") No. 213378 for LYBALVI®.

3. Plaintiff Alkermes Pharma Ireland Limited is an entity organized and existing under the laws of Ireland, with a principal place of business at Connaught House, 1 Burlington Road, Dublin 4, Ireland D04 C5Y6.

4. Upon information and belief, Defendant Apotex Corp. is an entity organized and existing under the laws of the state of Delaware, with a principal place of business at 2400 North Commerce Parkway Suite 400, Weston, Florida 33326.

5. Upon information and belief, Defendant Apotex Inc. is an entity organized and existing under the laws of Canada, with a principal place of business at 150 Signet Drive, Toronto, Ontario, M9L 1T9, Canada.

6. Upon information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Inc.

7. Upon information and belief, Apotex Inc. directs or controls the operations, management, and activities of Apotex Corp., including in the United States.

8. Upon 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.

9. Defendant Apotex Inc. holds Abbreviated New Drug Application ("ANDA") No. 220455.

10. Upon information and belief, Defendants have been acting in concert with respect to the preparation and submission of ANDA No. 220455 and the development of Apotex's proposed generic LYBALVI® product described therein ("Apotex's ANDA Product").

11. Upon information and belief, following any final FDA approval of ANDA No. 220455, Defendants will market, distribute, sell, offer for sale, and/or import Apotex's ANDA Product throughout the United States.

NATURE OF THE ACTION

12. This is a civil action for patent infringement of U.S. Patent Nos. 11,707,466 (the "'466 Patent"), 11,951,111 (the "'111 Patent"), and 12,390,474 (the "'474 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, and the Declaratory Judgment Act, 28 U.S.C. § 2201-02.

13. This action is based on Defendants' submission to the FDA of ANDA No. 220455, seeking approval to manufacture and sell a generic version of LYBALVI® prior to the expiration of the '111 Patent and '466 Patent, which are listed in Approved Drug Products with Therapeutic Equivalence Evaluations (an FDA publication commonly known as the "Orange Book") for LYBALVI®, and the '474 Patent, which was listed in the Orange Book for LYBALVI® on or about August 20, 2025.

14. Defendants have infringed one or more claims of the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A) by virtue of their filing of ANDA No. 220455 with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking final FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of a generic version of LYBALVI® prior to the expiration of the Patents-in-Suit, or any extensions thereof.

15. Defendants will infringe one or more claims of the Patents-in-Suit under 35 U.S.C. § 271 (a), (b), and/or (c) should they engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into, the United States of a generic version of LYBALVI® prior to the expiration of the Patents-in Suit, or any extension thereof.

JURISDICTION AND VENUE

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and/or 35 U.S.C. § 271. This Court may declare the rights

and other legal relations of the parties under 28 U.S.C. §§ 2201-02 because this action is an actual controversy within the Court's jurisdiction.

17. Defendants have committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Alkermes. Alkermes manufactures LYBALVI® for sale and use throughout the United States, including in New Jersey. Upon information and belief and as indicated in Apotex's Notice Letter, Defendants prepared and filed ANDA No. 220455 with the intention of seeking to market Apotex's ANDA Product nationwide, including in New Jersey.

18. Upon information and belief, Defendants plan to sell Apotex's proposed generic LYBALVI® product in the State of New Jersey, list Apotex's ANDA Product in the State of New Jersey's prescription drug formulary, and seek Medicaid reimbursements for sales of Apotex's ANDA Product in the State of New Jersey, either directly or through one or more of their wholly owned subsidiaries, agents, affiliates, and/or alter egos.

19. Upon information and belief, Defendants know and intend that Apotex's ANDA Product will be distributed and sold in New Jersey and will thereby displace sales of LYBALVI®, causing injury to Alkermes. Defendants intend to take advantage of their established channels of distribution in New Jersey for the sale of Apotex's ANDA Product.

20. For at least the reasons above, and for other reasons that will be presented to the Court if jurisdiction is challenged, Defendants are subject to personal jurisdiction in New Jersey, and it would not be unfair or unreasonable for Defendants to litigate this action in this Court.

21. This Court has personal jurisdiction over Apotex Inc. because, *inter alia*, Apotex Inc.: (1) has purposely availed itself of the privilege of doing business in New Jersey directly or indirectly through its subsidiary, agent, and/or alter ego; (2) upon information and belief, maintains pervasive, continuous, and systematic contacts with the State of New Jersey, including the

marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey; (3) upon information and belief, derives substantial revenue from the sale of its products in New Jersey; and (4) upon information and belief, intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute Apotex's ANDA Product in New Jersey.

22. Alternatively, this Court may exercise jurisdiction over Apotex Inc. pursuant to Fed. R. Civ. P. 4(k)(2) because, *inter alia*, (1) Plaintiffs' claims arise under federal law; (2) Apotex Inc. is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) Apotex Inc. has sufficient contacts with the United States as a whole, including, but not limited to, by submitting or causing to be submitted various ANDAs to the FDA and manufacturing, importing, offering to sell, or selling pharmaceutical products throughout the United States, such that this Court's exercise of jurisdiction over Apotex Inc. satisfies due process.

23. The Court also has personal jurisdiction over Defendant Apotex Inc. because it has previously litigated patent disputes in the District of New Jersey and consented to or did not contest personal jurisdiction in this Court for the purposes of those actions, and has asserted counterclaims in those actions, including in at least *Supernus Pharmaceuticals, Inc. v. Apotex Inc., et al.*, No. 20-cv-07870 (D.N.J.); *Valeant Pharmaceuticals North America, et al. v. Apotex Inc., et al.*, 3:18-cv-14202 (D.N.J.); *Boehringer Ingelheim Pharmaceuticals, Inc., et al. v. Apotex Inc., et al.*, No. 18-cv-11350 (D.N.J.).

24. This Court has personal jurisdiction over Apotex Corp. because, *inter alia*, Apotex Corp.: (1) has purposely availed itself of the privilege of doing business in New Jersey, including, *inter alia*, by registering with the State of New Jersey's Department of Health as a wholesaler under Registration No. 5003192; (2) imports generic versions of branded pharmaceutical products for sale and use throughout the United States, including in the State of New Jersey; (3) markets, distributes, and sells generic versions of branded pharmaceutical products throughout the United

States, including in the State of New Jersey; and (5) upon information and belief, derives substantial revenue from the sale of its products in New Jersey.

25. This Court also has personal jurisdiction over Apotex Corp. because, *inter alia*, Apotex Corp. has committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement, including acts in the State of New Jersey, that have led to foreseeable harm and injury to Plaintiffs in the State of New Jersey.

26. The Court also has personal jurisdiction over Defendant Apotex Corp. because it has previously litigated patent disputes in the District of New Jersey and consented to or did not contest personal jurisdiction in this Court for the purposes of those actions, and has asserted counterclaims in those actions, including in at least *AstraZeneca AB, et al. v. Apotex Corp., et al.*, Civil Action No. 15-cv-03379 (D.N.J.); *Supernus Pharmaceuticals, Inc. v. Apotex Inc., et al.*, No. 20-cv-07870 (D.N.J.); *Valent Pharmaceuticals North America, et al. v. Apotex Inc., et al.*, No. 3:18-cv-14202 (D.N.J.); *Boehringer Ingelheim Pharmaceuticals, Inc., et al. v. Apotex Inc., et al.*, No. 18-cv-11350 (D.N.J.).

27. Venue is proper in this Court as to Apotex Inc. under 28 U.S.C. §§ 1391 and 1400(b) because Apotex Inc. is a foreign corporation and may be sued in any judicial district in the United States in which Apotex Inc. is subject to the Court's personal jurisdiction.

28. Venue is proper in this Court as to Apotex Corp. under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because Apotex Corp. has a regular and established place of business in New Jersey at least because, upon information and belief, they: (1) have, in concert with Apotex Inc., sought final approval from the FDA to market and sell Apotex's ANDA Product in New Jersey; (2) have engaged in regular and established business contacts with New Jersey by, among other things, marketing, making, shipping, using, offering to sell, or selling pharmaceutical products in New Jersey, and deriving substantial revenue from such activities; and (3) upon information and

belief, Defendant Apotex Corp. is registered with the State of New Jersey's Department of Health as a wholesaler under Registration No. 5003192.

29. Upon information and belief, Defendants: (1) have sought approval from the FDA to market and sell Apotex's ANDA Product in New Jersey; and (2) have engaged in regular and established business contacts with New Jersey by, among other things, marketing, making, importing, using, offering to sell, or selling pharmaceutical products in New Jersey; and (3) deriving substantial revenue from such activities.

30. Upon information and belief, Defendants, directly and/or through one or more of their affiliates, agents, and/or alter egos, have an extensive network of physicians, medical facilities, wholesalers, and distributors in this Judicial District and intend to take advantage of their established channels of distribution in New Jersey for the sale of Apotex's ANDA Product.

THE PATENTS-IN-SUIT

31. U.S. Patent No. 11,707,466, entitled "Immediate Release Multilayer Tablet," was duly and legally issued on July 25, 2023. A true and correct copy of the '466 Patent is attached hereto as "Exhibit A."

32. Alkermes Pharma Ireland Limited is the assignee of, and holds all rights, title, and interest in, the '466 Patent.

33. The '466 Patent currently expires on November 12, 2041.

34. U.S. Patent No. 11,951,111, entitled "Immediate Release Multilayer Tablet," was duly and legally issued on April 9, 2024. A true and correct copy of the '111 Patent is attached hereto as "Exhibit B."

35. Alkermes Pharma Ireland Limited is the assignee of, and holds all rights, title, and interest in, the '111 Patent.

36. The '111 Patent currently expires on November 12, 2041.

37. U.S. Patent No. 12,390,474, entitled "Immediate Release Multilayer Tablet," was duly and legally issued on August 19, 2025. A true and correct copy of the '474 Patent is attached hereto as "Exhibit C."

38. Alkermes Pharma Ireland Limited is the assignee of, and holds all rights, title, and interest in, the '474 Patent.

39. The '474 Patent currently expires on November 12, 2041.

ALKERMES' LYBALVI® PRODUCT

40. Antipsychotic medications are among the most important therapeutic tools for treating various psychotic disorders.

41. Atypical antipsychotics, also known as second generation antipsychotics, are the first line of treatment for patients with bipolar disorder and schizophrenia. However, excessive weight gain associated with atypical antipsychotics is significant given its impact on general health and psychological issues. Unwanted weight gain is one of the most common reasons for a patient's noncompliance with an atypical antipsychotic administration schedule, ultimately leading to the failure of the treatment. Olanzapine, an atypical antipsychotic prescribed for the treatment of bipolar disorder and schizophrenia, is known to cause significant weight gain.

42. To address the unwanted side effects of weight gain associated with the atypical antipsychotic olanzapine, Alkermes developed LYBALVI®.

43. Alkermes is the holder of New Drug Application ("NDA") No. 213378, which was approved by the FDA on May 28, 2021, for the marketing and sale of olanzapine/samidorphan in the United States under the trade name "LYBALVI®." Alkermes markets and sells LYBALVI® in the United States pursuant to NDA 213378.

44. LYBALVI® is a combination product including two active pharmaceutical agents: an antipsychotic, olanzapine, and opioid receptor antagonist, samidorphan. Olanzapine is an

atypical antipsychotic. Samidorphan helps counteract some of the metabolic side effects of olanzapine.

45. LYBALVI® is commercially marketed and sold in four strengths : LYBALVI® 5mg/10mg (olanzapine/samidorphan); LYBALVI® 10mg/10mg (olanzapine/samidorphan); LYBALVI® 15mg/10mg (olanzapine/samidorphan); and LYBALVI® 20mg/10mg (olanzapine/samidorphan).

46. The FDA Orange Book for NDA No. 213378 for LYBALVI® lists, among several other patents, the Patents-in-Suit.

APOTEX'S LYBALVI® ANDA PRODUCT

47. By letter dated July 14, 2025, and received by Alkermes no earlier than on July 15, 2025 (the "Notice Letter"), Apotex notified Alkermes that Apotex had submitted ANDA No. 220455 to the FDA for a generic version of LYBALVI®.

48. The Notice Letter states that Apotex seeks approval from the FDA to engage in the commercial manufacture, use, and sale of Apotex's ANDA Product before the expiration of the '466 and '111 Patents. Upon information and belief, Apotex intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of Apotex's ANDA Product promptly upon receiving final FDA approval to do so.

49. By submitting ANDA No. 220455, Apotex has represented to the FDA that Apotex's ANDA Product has the same active ingredient, dosage form, and strengths as LYBALVI® and is bioequivalent to LYBALVI®.

50. In the Notice Letter, Apotex stated that ANDA No. 220455 included a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '111 and '466 Patents. Apotex also contended that the '111 and '466 Patents will not be infringed by the commercial manufacture, use, or sale of Apotex's ANDA product.

51. Upon information and belief, Apotex had knowledge of the '111 and '466 Patents when it submitted ANDA No. 220455 to the FDA.

52. Upon information and belief, Apotex has knowledge of the '474 Patent, since it was issued on August 19, 2025 and was listed in the Orange Book for LYBALVI® on or about August 20, 2025.

53. Upon information and belief, Apotex intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product immediately and imminently upon final FDA approval of ANDA No. 220455.

54. On or about August 14, 2025, pursuant to an Offer of Confidential Access set forth in the Notice Letter and an agreement between the Parties on August 13, 2025, Apotex produced the entirety of ANDA No. 220455, as filed with the FDA, to Alkermes. Apotex refused to provide samples of its ANDA Product or components.

55. This action is being commenced before the expiration of forty-five days from the date of Alkermes' receipt of the Notice Letter.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,707,466 UNDER 35 U.S.C. § 271 BY DEFENDANTS

56. Plaintiffs incorporate each of the preceding paragraphs 1-55 as if fully set forth herein.

57. Defendants' submission of ANDA No. 220455, with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Product before the expiration of the '466 Patent constituted an act of infringement of one or more claims of the '466 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

58. Upon information and belief, Defendants actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the preparation, submission, and maintenance of ANDA No. 220455 to the FDA.

59. After final FDA approval of ANDA No. 220455, Defendants will infringe one or more claims of the '466 Patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Apotex's ANDA 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 final FDA approval of ANDA No. 220455 shall be no earlier than the expiration of the '466 Patent and any additional periods of exclusivity.

60. Defendants are aware, have knowledge of, or are wilfully blind to the fact that healthcare providers will prescribe, and patients will take Apotex's ANDA Product, and therefore will infringe at least one claim of the '466 Patent.

61. Defendants are aware, have knowledge of, or are willfully blind to the fact that they will induce direct infringement of at least one claim of the '466 Patent, either literally or under the doctrine of equivalents.

62. Defendants know or should know that Apotex's ANDA Product is especially adapted for a use that infringes the '466 Patent, and there is no substantial non-infringing use.

63. Defendants have knowledge and are aware of the '466 Patent, as evidenced by Defendants' Notice Letter.

64. Unless Defendants are enjoined from directly or indirectly infringing the'466 Patent, Alkermes will suffer substantial and irreparable harm for which Alkermes has no adequate remedy at law.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,707,466 BY DEFENDANTS

65. Plaintiffs incorporate each of the preceding paragraphs 1-64 as if fully set forth herein.

66. Alkermes' claims also arise under the Declaratory Judgment Act, 28 U.S.C. § 2201 – 02.

67. Upon information and belief, upon final FDA approval of ANDA No. 220455, Defendants intend to, and will, infringe one or more claims of the '466 Patent, under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents by the manufacture, use, sale, or importation of Apotex's ANDA Product, unless enjoined by the Court.

68. Upon information and belief, Defendants intend to, and will, actively induce infringement of one or more claims of the '466 Patent, under 35 U.S.C. § 271(b) if/when ANDA No. 220455 is approved by marketing Apotex's ANDA Product and encouraging doctors and patients to infringe the '466 Patent, unless enjoined by the Court.

69. Defendants have knowledge and are aware of the '466 Patent, as evidenced by Defendants' Notice Letter.

70. Upon information and belief, Defendants will contribute to infringement of one or more claims of the '466 Patent under 35 U.S.C. § 271(c) if/when ANDA No. 220455 is approved, unless enjoined by the Court, because Defendants know or should know that Apotex's ANDA Product is especially made or adapted for use that infringes the '466 Patent, and Apotex's ANDA Product is not suitable for substantial noninfringing use.

71. Defendants' infringement is imminent following final FDA approval of ANDA No. 220455.

72. Defendants have notified Alkermes of the submission of ANDA No. 220455 seeking approval to engage in the manufacture, use, sale, or importation of Apotex's ANDA Product before the expiration of the '466 Patent.

73. Upon information and belief, Defendants' infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Apotex's ANDA Product in the United States, will begin immediately after final FDA approval.

74. Thus, a real, substantial, and continuing justiciable controversy exists between the parties hereto as to the infringement of the '466 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

75. Unless Defendants are enjoined from directly or indirectly infringing the '466 Patent, Alkermes will suffer substantial and irreparable harm for which Alkermes has no adequate remedy at law.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 11,951,111 UNDER 35 U.S.C. § 271 BY DEFENDANTS

76. Plaintiffs incorporate each of the preceding paragraphs 1-75 as if fully set forth herein.

77. Defendants' submission of ANDA No. 220455, with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Product before the expiration of the '111 Patent constituted an act of infringement of one or more claims of the '111 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

78. Upon information and belief, Defendants actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the preparation, submission, and maintenance of ANDA No. 220455 to the FDA.

79. After final FDA approval of ANDA No. 220455, Defendants will infringe one or more claims of the '111 Patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Apotex's ANDA 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 final FDA approval of ANDA No. 220455 shall be no earlier than the expiration of the '111 Patent and any additional periods of exclusivity.

80. Defendants are aware, have knowledge of, or are wilfully blind to the fact that healthcare providers will prescribe, and patients will take Apotex's ANDA Product, and therefore will infringe at least one claim of the '111 Patent.

81. Defendants are aware, have knowledge of, or are wilfully blind to the fact that they will induce direct infringement of at least one claim of the '111 Patent, either literally or under the doctrine of equivalents.

82. Defendants know or should know that Apotex's ANDA Product is especially adapted for a use that infringes the '111 Patent, and there is no substantial non-infringing use.

83. Defendants have knowledge and are aware of the '111 Patent, as evidenced by Defendants' Notice Letter.

84. Unless Defendants are enjoined from directly or indirectly infringing the '111 Patent, Alkermes will suffer substantial and irreparable harm for which Alkermes has no adequate remedy at law.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,951,111 BY DEFENDANTS

85. Plaintiffs incorporate each of the preceding paragraphs 1-84 as if fully set forth herein.

86. Alkermes' claims also arise under the Declaratory Judgment Act, 28 U.S.C. § 2201 – 02.

87. Upon information and belief, upon final FDA approval of ANDA No. 220455, Defendants intend to, and will, infringe one or more claims of the '111 Patent, under 35 U.S.C.

§ 271(a) either literally or under the doctrine of equivalents by the manufacture, use, sale, or importation of Apotex's ANDA Product, unless enjoined by the Court.

88. Upon information and belief, Defendants intend to, and will, actively induce infringement of one or more claims of the '111 Patent, under 35 U.S.C. § 271(b) if/when ANDA No. 220455 is approved by marketing Apotex's ANDA Product and encouraging doctors and patients to infringe the '111 Patent, unless enjoined by the Court.

89. Defendants have knowledge and are aware of the '111 Patent, as evidenced by Defendants' Notice Letter.

90. Upon information and belief, Defendants will contribute to infringement of one or more claims of the '111 Patent under 35 U.S.C. § 271(c) if/when ANDA No. 220455 is approved, unless enjoined by the Court, because Defendants know or should know that Apotex's ANDA Product is especially made or adapted for use that infringes the '111 Patent, and Apotex's ANDA Product is not suitable for substantial noninfringing use.

91. Defendants' infringement is imminent following final FDA approval of ANDA No. 220455.

92. Defendants have notified Alkermes of the submission of ANDA No. 220455 seeking approval to engage in the manufacture, use, sale, or importation of Apotex's ANDA Product before the expiration of the '111 Patent.

93. Upon information and belief, Defendants' infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Apotex's ANDA Product in the United States, will begin immediately after final FDA approval.

94. Thus, a real, substantial, and continuing justiciable controversy exists between the parties hereto as to the infringement of the '111 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

95. Unless Defendants are enjoined from directly or indirectly infringing the '111 Patent, Alkermes will suffer substantial and irreparable harm for which Alkermes has no adequate remedy at law.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 12,290,474 UNDER 35 U.S.C. § 271 BY DEFENDANTS

96. Plaintiffs incorporate each of the preceding paragraphs 1-95 as if fully set forth herein.

97. Defendants' submission of ANDA No. 220455 to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Product before the expiration of the '474 Patent constitutes an act of infringement of one or more claims of the '474 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

98. Upon information and belief, Defendants will submit a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '474 Patent in connection with Defendants' submission of ANDA No. 220455.

99. Upon information and belief, Defendants actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the preparation, submission, and maintenance of ANDA No. 220455 to the FDA.

100. After final FDA approval of ANDA No. 220455, Defendants will infringe one or more claims of the '474 Patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Apotex's ANDA 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 final FDA approval of ANDA No. 220455 shall be no earlier than the expiration of the '474 Patent and any additional periods of exclusivity.

101. Defendants are aware, have knowledge of, or are wilfully blind to the fact that healthcare providers will prescribe, and patients will take Apotex's ANDA Product, and therefore will infringe at least one claim of the '474 Patent.

102. Defendants are aware, have knowledge of, or are wilfully blind to the fact that they will induce direct infringement of at least one claim of the '474 Patent, either literally or under the doctrine of equivalents.

103. Defendants know or should know that their proposed generic LYBALVI® product is especially adapted for a use that infringes the '474 Patent, and there is no substantial non-infringing use.

104. The '474 Patent was submitted for listing in the Orange Book on August 19, 2025 and was listed in the Orange Book on or about August 20, 2025, providing public notice of the '474 Patent. Upon information and belief, Defendants have or should have knowledge of the '474 Patent, as evidenced by the public notice of the '474 Patent.

105. Unless Defendants are enjoined from directly or indirectly infringing the '474 Patent, Alkermes will suffer substantial and irreparable harm for which Alkermes has no adequate remedy at law.

COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 12,390,474 BY DEFENDANTS

106. Plaintiffs incorporate each of the preceding paragraphs 1-105 as if fully set forth herein.

107. Alkermes' claims also arise under the Declaratory Judgment Act, 28 U.S.C. § 2201 – 02.

108. Upon information and belief, upon final FDA approval of ANDA No. 220455, Defendants intend to, and will, infringe one or more claims of the '474 Patent, under 35 U.S.C.

§ 271(a) either literally or under the doctrine of equivalents by the manufacture, use, sale, or importation of Apotex's ANDA Product, unless enjoined by the Court.

109. Upon information and belief, Defendants intend to, and will, actively induce infringement of one or more claims of the '474 Patent, under 35 U.S.C. § 271(b) when ANDA No. 220455 is approved by marketing Apotex's ANDA Product and encouraging doctors and patients to infringe the '474 Patent, unless enjoined by the Court.

110. The '474 Patent was submitted for listing in the Orange Book on August 19, 2025 and was listed in the Orange Book on or about August 20, 2025, providing public notice of the '474 Patent. Upon information and belief, Defendants have or should have knowledge of the '474 Patent, as evidenced by the public notice of the '474 Patent.

111. Upon information and belief, Defendants will contribute to infringement of one or more claims of the '474 Patent under 35 U.S.C. § 271(c) if/when ANDA No. 220455 is approved, unless enjoined by the Court, because Defendants know or should know that Apotex's ANDA Product is especially made or adapted for use in infringing the '474 Patent, and Apotex's ANDA Product is not suitable for substantial noninfringing use.

112. Defendants' infringement is imminent following final FDA approval of ANDA No. 220455.

113. Defendants have notified Alkermes of the submission of ANDA No. 220455 seeking approval to engage in the manufacture, use, sale, or importation of Apotex's ANDA Product before the expiration of the '474 Patent.

114. Upon information and belief, Defendants' infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Apotex's ANDA Product in the United States, will begin immediately after final FDA approval.

115. Thus, a real, substantial, and continuing justiciable controversy exists between the parties hereto as to the infringement of the '474 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

116. Unless Defendants are enjoined from directly or indirectly infringing the '474 Patent, Alkermes will suffer substantial and irreparable harm for which Alkermes has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Alkermes asks that this Court grant the following relief:

A. A Judgment that the claims of the Patents-in-Suit are infringed by Apotex's submission of ANDA No. 220455 under 35 U.S.C. § 271(e)(2)(A);

B. A Declaratory Judgment that the commercial manufacture, use, offer to sell, or sale in, or importation into, the United States of Apotex's ANDA Product prior to the expiration of the Patents-in-Suit will infringe the Patents-in-Suit, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c);

C. A Judgment that the Patents-in-Suit are not invalid or unenforceable;

D. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any final FDA approval of Apotex's ANDA No. 220455 shall not be earlier than the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Alkermes is or becomes entitled;

E. An Order enjoining Apotex, and its affiliates, subsidiaries, and each of its officers, agents, servants and employees, and those acting in privity or concert with Apotex, from making, using offering to sell, selling, or importing Apotex's ANDA Product until after the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Alkermes is or becomes entitled;

F. Damages or other monetary relief, including costs, fees, pre-judgment interest and post-judgment interest to Alkermes if Apotex engages in the commercial manufacture, use, offers to sell, or sale in, or importation into, the United States of Apotex's ANDA Product prior to the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Alkermes is or becomes entitled;

G. A Declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285; and

H. Such further and other relief as this Court deems proper and just.

Dated: August 27, 2025

By: s/ Charles M. Lizza

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LOCAL CIVIL RULE 11.2 & 40.1 CERTIFICATION

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that this matter is related to *Alkermes, Inc. v. Teva Pharmaceuticals, Inc.*, No. 25-14685 (KMW) (D.N.J.) because it involves the same plaintiffs, the same patents, and because Defendants are seeking to make a generic version of the same branded pharmaceutical product.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: August 27, 2025

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