Charles M. Lizza
Sarah A. Sullivan
Alexander L. Callo
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiffs Alkermes, Inc. and Alkermes Pharma Ireland Limited

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ALKERMES, INC. and ALKERMES PHARMA IRELAND LIMITED, Plaintiffs, v. TEVA PHARMACEUTICALS, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., and PLIVA HRVATSKA D.O.O., Defendants.	C.A. No. 25-_____ (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 Teva Pharmaceuticals, Inc. ("Teva Pharms."), Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), and PLIVA Hrvatska d.o.o. ("PLIVA") (together, "Teva" 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, MA 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 Teva Pharmaceutical Industries Ltd. is an entity organized and existing under the laws of Israel, having a principal place of business at 5 Basel Street, Petah, Tikva, 49131, Israel.

5. Upon information and belief, Defendant Teva Pharmaceuticals, Inc. is an entity organized and existing under the laws of the State of Delaware and has a principal place of business in New Jersey at 400 Interpace Parkway #3, Parsippany, New Jersey 07054.

6. Upon information and belief, Defendant PLIVA Hrvatska d.o.o. is an entity organized and existing under the laws of Croatia, having a principal place of business at Prilaz baruna Filipovica 25, Zagreb 10000, Croatia.

7. Upon information and belief, Teva Pharms. and PLIVA are wholly owned subsidiaries of Teva Ltd.

8. Upon information and belief, Teva Ltd. directs or controls the operations, management, and activities of Teva Pharms. and PLIVA, including in the United States.

9. Upon information and belief, Teva Ltd., Teva Pharms., and PLIVA are agents of each other and/or operate in concert as integrated parts of the same business group.

10. Defendant Teva Pharms. holds Abbreviated New Drug Application ("ANDA") No. 220379.

11. Upon information and belief, Defendants have been acting in concert with respect to the preparation and submission of ANDA No. 220379 and the development of Teva's proposed generic LYBALVI® product described therein ("the Teva ANDA Product" or "Teva's ANDA Product").

12. Upon information and belief, Defendants have been acting in concert with respect to the development of Teva's ANDA Product.

13. Upon information and belief, following any final FDA approval of ANDA No. 220379, Defendants will market, distribute, sell, offer for sale, and/or import Teva's ANDA Product throughout the United States.

NATURE OF THE ACTION

14. This is a civil action for patent infringement of 11,707,466 (the "'466 Patent") and 11,951,111 (the "'111 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.

15. This action is based on Defendant's submission to the FDA of ANDA No. 220379, seeking approval to manufacture and sell a generic version of LYBALVI® prior to the expiration of the Patents-in-Suit, which are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for LYBALVI®.

16. 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. 220379 with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking 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.

17. 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

18. 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.

19. 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 Teva's Notice Letter, Defendants prepared and filed ANDA No. 220379 with the intention of seeking to market Teva's ANDA Product nationwide, including in New Jersey.

20. Upon information and belief, Defendants plan to sell Teva's proposed generic LYBALVI® product in the State of New Jersey, list Teva's ANDA Product in the State of New Jersey's prescription drug formulary, and seek Medicaid reimbursements for sales of Teva'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.

21. Upon information and belief, Defendants know and intend that Teva'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 Teva's ANDA Product.

22. Upon information and belief, Defendants worked in concert to prepare and file ANDA No. 220379 in Parsippany, New Jersey, which constituted an act of infringement under 35 U.S.C. § 271(e)(2).

23. 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.

24. This Court has personal jurisdiction over Teva Ltd. because, *inter alia*, Teva Ltd.: (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 Teva's ANDA Product in New Jersey.

25. Alternatively, this Court may exercise jurisdiction over Teva Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because, *inter alia*, (1) Plaintiffs' claims arise under federal law; (2) Teva Ltd. is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) Teva Ltd. 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 Teva Ltd. satisfies due process.

26. This Court has personal jurisdiction over Teva Pharms. because, *inter alia*, Teva Pharms. (1) has principal place of business in New Jersey at 400 Interpace Parkway #3, Parsippany, New Jersey 07054; (2) has purposely availed itself of the privilege of doing business in New Jersey, including, *inter alia*, by registering with the New Jersey Department of the Treasury in Parsippany, NJ under Entity Identification No. 0450614134; (3) imports generic versions of branded pharmaceutical products for sale and use throughout the United States, including in the State of New Jersey; (4) 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.

27. This Court also has personal jurisdiction over Teva Pharms. because, *inter alia*, Teva Pharms. 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.

28. This Court also has personal jurisdiction over Defendant Teva Pharms. 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 purposes of those actions, and has asserted counterclaims in those actions, including in at least *Aurinia Pharmaceuticals Inc. v. Teva Pharmaceuticals, Inc.*, No. 25-cv-03267 (D.N.J.); *Jazz Pharmaceuticals Ireland Limited v. Teva Pharmaceuticals, Inc.*, No. 24-cv-08785 (D.N.J.); *Catalyst Pharmaceuticals, Inc. et al. v. Teva Pharmaceuticals, Inc., et al.*, No. 23-01190 (D.N.J.); and *GW Research Limited v. Teva Pharmaceuticals, Inc., et al*, No. 23-cv-00018 (D.N.J.).

29. This Court has personal jurisdiction over Defendant PLIVA because PLIVA, in concert with its affiliates, Teva Ltd. and Teva Pharms., among other things, has committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C.

§ 271(e)(2) by preparing portions of ANDA No. 220379, and intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c) in New Jersey. These acts have led and will continue to lead to foreseeable harm to Alkermes. For example, upon information and belief, following final approval of ANDA No. 220379, PLIVA, in concert with its affiliates, Teva Ltd. and Teva Pharms., will make, use, import, sell, and/or offer for sale the Teva ANDA Product in the United States, including in New Jersey, prior to the expiration of the Patents-in-Suit.

30. This Court has personal jurisdiction over PLIVA because, *inter alia*, PLIVA: (1) has purposely availed itself of the privilege of doing business in New Jersey directly or indirectly through its affiliates, Teva Ltd. and Teva Pharms.; (2) upon information and belief, maintains pervasive, continuous, and systematic contacts with the State of New Jersey, including the marketing, distribution, importation, and/or sale of generic pharmaceutical drugs in New Jersey; (3) upon information and belief, derives substantial revenue from the importation and/or sale of its products in New Jersey; and (4) upon information and belief, intends to, directly or indirectly through its affiliates, Teva Ltd. and Teva Pharms., market, import, sell, or distribute Teva's ANDA Product in New Jersey.

31. Alternatively, this Court may exercise jurisdiction over PLIVA pursuant to Fed. R. Civ. P. 4(k)(2) because, *inter alia*, (1) Plaintiffs' claims arise under federal law; (2) PLIVA is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) PLIVA has sufficient contacts with the United States as a whole, including, but not limited to, by submitting, contributing to the submission, 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 PLIVA satisfies due process.

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

33. Venue is proper in this Court as to Teva Pharms. under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because upon information and belief, Teva Pharms. has a regular and established place of business in New Jersey and has committed, and will commit further, acts of infringement in this Judicial District.

34. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b), because Teva Pharms. is registered with the State of New Jersey Department of the Treasury Division of Revenue & Enterprise Services as Registration No. 0450614134.

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

36. Defendants: (1) have sought approval from the FDA to market and sell Teva'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.

37. 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 Teva's ANDA Product.

THE PATENTS-IN-SUIT

38. 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."

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

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

41. 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."

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

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

ALKERMES' LYBALVI® PRODUCT

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

45. 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.

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

47. 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.

48. LYBALVI® is a combination product including two active pharmaceutical agents: an antipsychotic, olanzapine, and samidorphan. Samidorphan helps counteract some of the metabolic side effects of olanzapine, including weight gain.

49. 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).

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

TEVA'S LYBALVI® ANDA PRODUCT

51. By letter dated July 3, 2025, and received by Alkermes no earlier than on July 7, 2025 (the "Notice Letter"), Teva notified Alkermes that Teva had submitted ANDA No. 220379 to the FDA for a generic version of LYBALVI®.

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

53. By submitting ANDA No. 220379, Teva has represented to the FDA that the Teva ANDA Product has the same active ingredient, dosage form, and strengths as LYBALVI® and is bioequivalent to LYBALVI®.

54. In the Notice Letter, Teva stated that ANDA No. 220379 included a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the Patents-in-Suit. Teva also contended that the Patents-in-Suit will not be infringed by the commercial manufacture, use, or sale of the Teva ANDA product.

55. Upon information and belief, Teva had knowledge of the Patents-in-Suit when it submitted ANDA No. 220379 to the FDA.

56. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product immediately and imminently upon final FDA approval of ANDA No. 220379.

57. On or about August 1, 2025, pursuant to an Offer of Confidential Access set forth in the Notice Letter, Teva produced portions of its ANDA No. 220379 to Alkermes. Teva refused to produce the entirety of ANDA No. 220379 to Alkermes and refused to provide samples of its ANDA Product or components.

58. 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

59. Plaintiffs incorporate each of the preceding paragraphs 1-58 as if fully set forth herein.

60. Defendants' submission of ANDA No. 220379, 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 Teva'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.

61. 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. 220379 to the FDA.

62. After final FDA approval of ANDA No. 220379, 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 Teva'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. 220379 shall be no earlier than the expiration of the '466 Patent and any additional periods of exclusivity.

63. Defendants know, or should know, and intend that healthcare providers will prescribe, and patients will take, Teva's ANDA Product, and therefore will infringe at least one claim of the '466 Patent.

64. Defendants know or should know that they will induce direct infringement of at least one claim of the '466 Patent, either literally or under the doctrine of equivalents.

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

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

67. 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

68. Plaintiffs incorporate each of the preceding paragraphs 1-67 as if fully set forth herein.

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

70. Upon information and belief, upon final FDA approval of ANDA No. 220379, 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 Teva's ANDA Product, unless enjoined by the Court.

71. 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. 220379 is approved by marketing Teva's ANDA Product and encouraging doctors and patients to infringe the '466 Patent, unless enjoined by the Court.

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

73. 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. 220379 is approved, unless enjoined by the Court, because Defendants know or should know that the Teva's ANDA Product is especially made or adapted for use that infringes the '466 Patent, and Defendants' ANDA Product is not suitable for substantial noninfringing use.

74. Defendants' infringement is imminent following final FDA approval of ANDA No. 220379.

75. Defendants have notified Alkermes of the submission of ANDA No. 220379 and Defendants' intent in seeking approval to engage in the manufacture, use, sale, or importation of Teva's ANDA Product before the expiration of the '466 Patent.

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

77. 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.

78. 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

79. Plaintiffs incorporate each of the preceding paragraphs 1-78 as if fully set forth herein.

80. Defendants' submission of ANDA No. 220379, 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 Teva'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.

81. 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. 220379 to the FDA.

82. After final FDA approval of ANDA No. 220379, 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 Teva'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. 220379 shall be no earlier than the expiration of the '111 Patent and any additional periods of exclusivity.

83. Defendants know, or should know, and intend that healthcare providers will prescribe, and patients will take, Teva's ANDA Product, and therefore will infringe at least one claim of the '111 Patent.

84. Defendants know or should know that they will induce direct infringement of at least one claim of the '111 Patent, either literally or under the doctrine of equivalents.

85. Defendants know or should know that their proposed generic LYBALVI® product is especially adapted for a use that infringes the '111 Patent, and there is no substantial non-infringing use.

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

87. 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

88. Plaintiffs incorporate each of the preceding paragraphs 1-87 as if fully set forth herein.

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

90. Upon information and belief, upon final FDA approval of ANDA No. 220379, 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 Teva's ANDA Product, unless enjoined by the Court.

91. 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. 220379 is approved by marketing Teva's ANDA Product and encouraging doctors and patients to infringe the '111 Patent, unless enjoined by the Court.

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

93. 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. 220379 is approved, unless enjoined by the Court, because Defendants know or should know that the Teva's ANDA Product is especially made or adapted for use that infringes the '111 Patent, and Teva's ANDA Product is not suitable for substantial noninfringing use.

94. Defendants' infringement is imminent following final FDA approval of ANDA No. 220379.

95. Defendants have notified Alkermes of the submission of ANDA No. 220379 and Defendants' intent in seeking approval to engage in the manufacture, use, sale, or importation of Teva's ANDA Product before the expiration of the '111 Patent.

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

97. 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.

98. 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.

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 Teva's submission of ANDA No. 220379 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 Teva'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 Teva's ANDA No. 220379 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 Teva, and its affiliates, subsidiaries, and each of its officers, agents, servants and employees, and those acting in privity or concert with Teva, from making, using offering to sell, selling, or importing the Teva 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 Teva engages in the commercial manufacture, use, offers to sell, or sale in, or importation into, the United States of the Teva 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 15, 2025

By: s/ Charles M. Lizza

Charles M. Lizza
Sarah A. Sullivan
Alexander L. Callo
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiffs Alkermes, Inc. and Alkermes Pharma Ireland Limited

OF COUNSEL (*pro hac vice* forthcoming):

Nicholas Mitrokostas
John T. Bennett
Michael Wiper
Michael L. Jindia
ALLEN OVERY SHEARMAN STERLING US LLP
One Beacon Street
Boston, MA 02108
(857) 353 4500

Elizabeth Holland
Mena Gaballah
ALLEN OVERY SHEARMAN STERLING US LLP
599 Lexington Avenue
New York, NY 10022
(212) 848-4000

Jenny J. Zhang
Michelle Bone
ALLEN OVERY SHEARMAN STERLING US LLP
1101 New York Avenue, NW
Washington, D.C.
(202) 683-3800

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

I hereby 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 15, 2025

By: s/ Charles M. Lizza
Charles M. Lizza
Sarah A. Sullivan
Alexander L. Callo
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiffs Alkermes, Inc. and Alkermes Pharma Ireland Limited

OF COUNSEL (*pro hac vice* forthcoming):

Nicholas Mitrokostas
John T. Bennett
Michael Wiper
Michael L. Jindia
ALLEN OVERY SHEARMAN STERLING US LLP
One Beacon Street
Boston, MA 02108
(857) 353 4500

Elizabeth Holland
Mena Gaballah
ALLEN OVERY SHEARMAN STERLING US LLP
599 Lexington Avenue
New York, NY 10022
(212) 848-4000

Jenny J. Zhang
Michelle Bone
ALLEN OVERY SHEARMAN STERLING US LLP
1101 New York Avenue, NW
Washington, D.C.
(202) 683-3800