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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ALKERMES, INC. and ALKERMES PHARMA IRELAND LIMITED, Plaintiffs, v. TEVA PHARMACEUTICALS, INC., Defendant.	)	C.A. No. 25-14685 (KMW)(AMD)

DEFENDANT TEVA PHARMACEUTICAL, INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Defendant Teva Pharmaceuticals, Inc. ("Teva Pharms.")[1], by and through the undersigned attorneys, hereby submits its answer, affirmative defenses, and counterclaims to the First Amended Complaint of Alkermes, Inc. and Alkermes Pharma Ireland Limited (collectively, "Plaintiffs") as set forth below. This pleading is based upon Teva Pharms.'s knowledge as to its own activities, and upon information and belief as to the activities of others. Teva Pharms. denies all allegations except those specifically admitted below. *See* Fed. R. Civ. P. 8(b)(3).

RESPONSE TO 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.

ANSWER: Teva Pharms. lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

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

ANSWER: Teva Pharms. admits that Alkermes, Inc. is listed in the Orange Book as the holder of NDA No. 213378 for oral tablets containing 5 mg (eq 10 mg base) olanzapine and samidorphan L-malate, 10 mg (eq 10 mg base) olanzapine and samidorphan L-malate, 15 mg (eq 10 mg base) olanzapine and samidorphan L-malate, and 20 mg (eq 10 mg base) olanzapine and samidorphan L-malate as the active ingredients and that the brand name is listed as LYBALVI®. Teva Pharms. denies any remaining allegations in this paragraph.

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.

[1] In accordance with Dkt. No. 26, Teva Pharmaceutical Industries Ltd. and Pliva Hrvatska d.o.o. have been dismissed by stipulation and order and are no longer parties to this action, as reflected in the updated caption. Accordingly, all references herein to "Teva" or "Defendants" should be understood to refer to only the remaining Defendant Teva Pharms., and not to include Teva Pharmaceutical Industries Ltd. or Pliva Hrvatska d.o.o.

ANSWER: Teva Pharms. lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph therefore denies them.

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.

ANSWER: In accordance with Dkt. No. 26, all claims against Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and such allegations in this paragraph are therefore denied on that basis.

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.

ANSWER: Admitted.

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.

ANSWER: In accordance with Dkt. No. 26, all claims against Defendant PLIVA Hrvatska d.o.o. ("PLIVA") have been dismissed, and therefore no response is required as to allegations pertaining to Defendant PLIVA, and such allegations in this paragraph are therefore denied on that basis.

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

ANSWER: Teva Pharms. admits that it is a wholly owned subsidiary of Teva Ltd. Teva Pharms. denies any remaining allegations in this paragraph, including because PLIVA has been dismissed from the action. *See* Dkt. No. 26.

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.

ANSWER: In accordance with Dkt. No. 26, all claims against Teva Ltd. have been dismissed, therefore no response is required as to allegations pertaining to Teva Ltd., and such allegations in this paragraph are therefore denied on that basis. Teva Pharms. denies any remaining allegations contained in this paragraph.

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.

ANSWER: In accordance with Dkt. No. 26, all claims against Teva Ltd. and PLIVA have been dismissed, therefore no response is required as to allegations pertaining to Teva Ltd. and PLIVA, and such allegations in this paragraph are therefore denied on that basis. Teva Pharms. denies any remaining allegations contained in this paragraph.

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

ANSWER: Admitted.

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").

ANSWER: In accordance with Dkt. No. 26, all claims against Teva Ltd. and PLIVA have been dismissed, therefore no response is required as to allegations pertaining to Teva Ltd. and PLIVA, and such allegations in this paragraph are therefore denied on that basis. Further, Paragraph 11 contains legal conclusions to which no response is required. Teva Pharms. denies any remaining allegations in this paragraph.

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

ANSWER: In accordance with Dkt. No. 26, all claims against Teva Ltd. and PLIVA have been dismissed, therefore no response is required as to allegations pertaining to Teva Ltd. and PLIVA, and such allegations in this paragraph are therefore denied on that basis. Further, Paragraph

12 contains legal conclusions to which no response is required. Teva Pharms. denies any remaining allegations in this paragraph.

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.

ANSWER: Teva Pharms. admits that it submitted ANDA No. 220379 with the FDA to obtain approval to engage in the commercial manufacture, use, or sale of Olanzapine and Samidorphan Tablets, 5 mg/10 mg, 10 mg/10 mg, 15 mg/10 mg and 20 mg/10 mg ("Teva Pharms.'s Proposed ANDA Products"). Teva Pharms. denies any remaining allegations in this paragraph, including because all claims against Teva Ltd. and PLIVA have been dismissed.

RESPONSE TO NATURE OF THE ACTION

14. 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.

ANSWER: Paragraph 14 states legal conclusions to which no response is required. To the extent a response is required, Teva Pharms. admits that Plaintiffs purport to bring an action for patent infringement under the laws of the United States with respect to the Patents-in-Suit. Teva Pharms. denies the remaining allegations in this paragraph.

15. This action is based on Defendants' 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 '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.

ANSWER: Paragraph 15 states legal conclusions to which no response is required. To the extent a response is required, Teva Pharms. admits that Plaintiffs purport to bring an action for patent infringement under the laws of the United States with respect to the Patents-in-Suit. Teva Pharms.

also admits that it submitted ANDA No. 220379 with the FDA to obtain approval to engage in the commercial manufacture, use, or sale of Teva Pharms.'s Proposed ANDA Products. Teva Pharms. denies the remaining allegations in this paragraph, including because all claims against Teva Ltd. and PLIVA have been dismissed.

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.

ANSWER: Paragraph 16 states legal conclusions to which no response is required. To the extent a response is required, denied.

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.

ANSWER: Paragraph 17 states legal conclusions to which no response is required. To the extent a response is required, denied.

RESPONSE TO 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.

ANSWER: Paragraph 18 states legal conclusions to which no response is required. To the extent a response is required, and solely to conserve the resources of the parties and the Court, Teva Pharms. does not contest that this Court has subject matter jurisdiction over this action. Teva Pharms. denies any remaining allegations in this paragraph.

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.

ANSWER: Teva Pharms. admits that Teva Pharms. submitted ANDA No. 220379 seeking approval to engage in commercial manufacture, use, or sale of Teva Pharms.'s Proposed ANDA Products. Paragraph 19 states legal conclusions to which no response is required. To the extent a response is required, Teva's Pharms.'s July 3, 2025 Notice Letter speaks for itself. Teva Pharms. denies any remaining allegations in this paragraph, including because all claims against Teva Ltd. and PLIVA have been dismissed.

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.

ANSWER: Teva Pharms. admits that Teva Pharms. submitted ANDA No. 220379 seeking approval to engage in commercial manufacture, use, or sale of Teva Pharms.'s Proposed ANDA Products. Teva Pharms. denies any remaining allegations in this paragraph, including because all claims against Teva Ltd. and PLIVA have been dismissed.

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.

ANSWER: Paragraph 21 states legal conclusions to which no response is required. To the extent a response is required, and solely to conserve the resources of the parties and the Court, Teva Pharms. does not contest subject matter jurisdiction in this judicial district for the purposes of this action. Teva Pharms. denies any remaining allegations in this paragraph, including because all claims against Teva Ltd. and PLIVA have been dismissed.

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).

ANSWER: In accordance with Dkt. No. 26, all claims against Teva Ltd. and PLIVA have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd. and PLIVA, and such allegations in this paragraph are therefore denied on that basis. Further, Paragraph 22 contains legal conclusions to which no response is required. Teva Pharms. denies any remaining allegations in this paragraph.

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.

ANSWER: In accordance with Dkt. No. 26, all claims against Teva Ltd. and PLIVA have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd. and PLIVA, and such allegations in this paragraph are therefore denied on that basis. Further, Paragraph 23 contains legal conclusions to which no response is required. To the extent a response is required, Teva Pharms. does not contest personal jurisdiction in this judicial district for the purposes of this action. Teva Pharms. denies any remaining allegations in this paragraph.

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.

ANSWER: In accordance with Dkt. No. 26, all claims against Teva Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and such allegations in this paragraph are therefore denied on that basis. Teva Pharms. denies any remaining allegations contained in this paragraph.

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.

ANSWER: In accordance with Dkt. No. 26, all claims against Teva Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and such allegations in this paragraph are therefore denied on that basis. Teva Pharms. denies any remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 26 contains legal conclusions to which no response is required. To the extent a response is required, and solely to conserve the resources of the parties and Court, Teva Pharms. does not contest personal jurisdiction in this judicial district for purposes of this action. Teva Pharms. denies any remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 27 contains legal conclusions to which no response is required. To the extent a response is required, and solely to conserve the resources of the parties and Court, Teva Pharms. does not contest personal jurisdiction in this judicial district for purposes of this action. Teva Pharms. denies any remaining allegations contained in this paragraph.

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.).

ANSWER: Paragraph 28 contains legal conclusions to which no response is required. To the extent a response is required, and solely to conserve the resources of the parties and Court, Teva Pharms. does not contest personal jurisdiction in this judicial district for purposes of this action. Teva Pharms. denies any remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 29 contains legal conclusions to which no response is required. In accordance with Dkt. No. 26, all claims against PLIVA have been dismissed, and therefore no response is required as to allegations pertaining to PLIVA, and such allegations in this paragraph are therefore denied on that basis. Teva Pharms. denies any remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 30 contains legal conclusions to which no response is required. In accordance with Dkt. No. 26, all claims against PLIVA have been dismissed, and therefore no

response is required as to allegations pertaining to PLIVA, and such allegations in this paragraph are therefore denied on that basis. Teva Pharms. denies any remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 31 contains legal conclusions to which no response is required. In accordance with Dkt. No. 26, all claims against PLIVA have been dismissed, and therefore no response is required as to allegations pertaining to PLIVA, and such allegations in this paragraph are therefore denied on that basis. Teva Pharms. denies any remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 32 contains legal conclusions to which no response is required. In accordance with Dkt. No. 26, all claims against Teva Ltd. have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd., and such allegations in this paragraph are therefore denied on that basis. Teva Pharms. denies any remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 33 contains legal conclusions to which no response is required. To the extent a response is required, and solely to conserve the resources of the parties and Court, Teva

Pharms. does not contest venue in this judicial district for purposes of this action. Teva Pharms. denies any remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 34 contains legal conclusions to which no response is required. To the extent a response is required, and solely to conserve the resources of the parties and Court, Teva Pharms. does not contest venue in this judicial district for purposes of this action. Teva Pharms. denies any remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 35 contains legal conclusions to which no response is required. In accordance with Dkt. No. 26, all claims against PLIVA have been dismissed, and therefore no response is required as to allegations pertaining to PLIVA, and such allegations in this paragraph are therefore denied on that basis. Teva Pharms. denies any remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 36 contains legal conclusions to which no response is required. To the extent a response is required, and solely to conserve the resources of the parties and Court, Teva Pharms. does not contest venue or jurisdiction in this judicial district for purposes of this action. Teva Pharms. denies any remaining allegations contained in this paragraph, including because all claims against Teva Ltd. and PLIVA have been dismissed.

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.

ANSWER: Paragraph 37 contains legal conclusions to which no response is required. To the extent a response is required, and solely to conserve the resources of the parties and Court, Teva Pharms. does not contest venue or jurisdiction in this judicial district for purposes of this action. Teva Pharms. denies any remaining allegations contained in this paragraph, including because all claims against Teva Ltd. and PLIVA have been dismissed.

RESPONSE TO 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.".

ANSWER: Teva Pharms. admits that Exhibit A to the First Amended Complaint appears to be a copy of U.S. Patent No. 11,707,466 (the "'466 Patent"), which indicates on its face an issue date of July 25, 2023. Teva Pharms. further admits that the '466 Patent is titled "Immediate Release Multilayer Tablet." Teva Pharms. denies any remaining allegations contained in this paragraph.

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

ANSWER: Teva Pharms. admits that Exhibit A to the First Amended Complaint appears to be a copy of the '466 Patent, which indicates on its face that Alkermes Pharma Ireland Limited is the Assignee. Teva Pharms. lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations this paragraph and therefore denies them.

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

ANSWER: Teva Pharms. lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

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."

ANSWER: Teva Pharms. admits that Exhibit B to the First Amended Complaint appears to be a copy of U.S. Patent No. 11,951,111 (the "'111 Patent"), which indicates on its face an issue date of April 9, 2024. Teva Pharms. further admits that the '111 Patent is titled "Immediate Release Multilayer Tablet." Teva Pharms. denies any remaining allegations contained in this paragraph.

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

ANSWER: Teva Pharms. admits that Exhibit B to the First Amended Complaint appears to be a copy of the '111 Patent, which indicates on its face that Alkermes Pharma Ireland Limited is the Assignee. Teva Pharms. lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and therefore denies them.

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

ANSWER: Teva Pharms. lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

44. 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."

ANSWER: Teva Pharms. admits that Exhibit C to the First Amended Complaint appears to be a copy of U.S. Patent No. 12,390,474 (the "'474 Patent"), which indicates on its face an issue date of August 19, 2025. Teva Pharms. further admits that the '474 Patent is titled "Immediate Release Multilayer Tablet." Teva Pharms. denies any remaining allegations contained in this paragraph.

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

ANSWER: Teva Pharms. admits that Exhibit C to the First Amended Complaint appears to be a copy of the '474 Patent, which indicates on its face that Alkermes Pharma Ireland Limited is the Assignee. Teva Pharms. lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and therefore denies them.

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

ANSWER: Teva Pharms. lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

RESPONSE TO ALKERMES' LYBALVI® PRODUCT

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

ANSWER: Teva Pharms. lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

48. 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.

ANSWER: Teva Pharms. lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

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

ANSWER: Teva Pharms. lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

50. 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.

ANSWER: Paragraph 50 contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. admits that the Orange Book identifies Alkermes Inc. as the purported holder of NDA No. 213378 under the brand name LYBALVI®. Teva Pharms. denies any remaining allegations contained in this paragraph.

51. 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.

ANSWER: Teva Pharms. admits the Orange Book lists olanzapine and samidorphan l-malate as the two active ingredients in LYBALVI®. Teva Pharms. lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and therefore denies them.

52. 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).

ANSWER: On information and belief LYBALVI® is marketed and sold in the United States in the strengths according to the LYBALVI® prescribing information. The prescribing information speaks for itself. Teva Pharms. denies any remaining allegations contained in this paragraph.

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

ANSWER: Teva Pharms. admits that the Patents-in-Suit are listed in the Orange Book with respect to LYBALVI®. Plaintiffs caused the Patents-in-Suit to be listed in the Orange Book, and Teva Pharms. denies that the Patents-in-Suit were properly listed. Teva Pharms. denies any remaining allegations contained in this paragraph.

RESPONSE TO TEVA'S LYBALVI® ANDA PRODUCT

54. 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®.

ANSWER: Teva Pharms. admits that Teva Pharms. sent a Notice Letter to Plaintiffs dated July 3, 2025 and stating that Teva Pharms. submitted ANDA No. 220379 with the FDA to obtain approval to engage in the commercial manufacture, use, or sale of Teva Pharms.'s Proposed ANDA Products. Teva Pharms.'s Notice Letter speaks for itself. Teva Pharms. lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in this paragraph and therefore denies them.

55. 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.

ANSWER: Teva Pharms. admits that Teva Pharms. submitted ANDA No. 220379 with the FDA to obtain approval to engage in the commercial manufacture, use, or sale of Teva Pharms.'s Proposed ANDA Products. Teva Pharms.'s July 3, 2025 Notice Letter speaks for itself. Teva Pharms. denies any remaining allegations in this paragraph.

56. 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®.

ANSWER: Teva Pharms. admits that Teva Pharms. submitted ANDA No. 220379 with the FDA to obtain approval to engage in the commercial manufacture, use, or sale of Teva Pharms.'s Proposed ANDA Products. ANDA No. 220379 speaks for itself. Teva Pharms. denies any remaining allegations in this paragraph.

57. 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 '111 and '466 Patents. Teva also contended that the '111 and '466 Patents will not be infringed by the commercial manufacture, use, or sale of the Teva ANDA product.

ANSWER: Teva Pharms. admits that Teva Pharms. sent a Notice Letter to Plaintiffs on July 3, 2025 stating that Teva Pharms. submitted ANDA No. 220379 with the FDA to obtain approval to

engage in the commercial manufacture, use, or sale of Teva Pharms.'s Proposed ANDA Products. Teva Pharms.'s July 3, 2025 Notice Letter speaks for itself. Teva Pharms. denies any remaining allegations in this paragraph.

58. Upon information and belief, Teva had knowledge of the '111 and '466 Patents when it submitted ANDA No. 220379 to the FDA.

ANSWER: Paragraph 58 contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

59. 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.

ANSWER: Teva Pharms. admits that Teva Pharms. submitted ANDA No. 220379 with the FDA to obtain approval to engage in the commercial manufacture, use, or sale of Teva Pharms.'s Proposed ANDA Products. Teva Pharms. denies any remaining allegations in this paragraph.

60. 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.

ANSWER: Teva Pharms. admits that on or about August 1, 2025, Teva Pharms. provided a copy of modules 1, 2, and 3 of its ANDA No. 220379 to Alkermes. Teva Pharms. denies any remaining allegations in this paragraph.

61. This action was commenced before the expiration of forty-five days from the date of Alkermes' receipt of the Notice Letter.

ANSWER: Teva Pharms. admits that Plaintiffs filed the initial Complaint in this matter on August 15, 2025. Teva Pharms. lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

RESPONSE TO COUNT I
(Infringement of the '466 Patent under 35 U.S.C. § 271 by Defendants)

62. Plaintiffs incorporate each of the preceding paragraphs 1-61 as if fully set forth herein.

ANSWER: Teva Pharms. incorporates its responses to the preceding paragraphs as if fully set forth herein.

63. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

64. 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.

ANSWER: Teva Pharms. admits that Teva Pharms. submitted ANDA No. 220379 with the FDA to obtain approval to engage in the commercial manufacture, use, or sale of Teva Pharms.'s Proposed ANDA Products. Furthermore, in accordance with Dkt. No. 26, all claims against Teva Ltd. and PLIVA have been dismissed, and therefore no response is required as to allegations pertaining to Teva Ltd. and PLIVA, and such allegations in this paragraph are therefore denied on that basis. Teva Pharms. denies any remaining allegations in this paragraph.

65. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

66. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

67. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

68. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

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

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms.'s July 3, 2025 Notice Letter speaks for itself. Teva Pharms. denies any remaining allegations in this paragraph.

70. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

RESPONSE TO COUNT II
(Declaratory Judgment of Infringement of U.S. Patent No. 11,707,466 Patent by Defendants)

71. Plaintiffs incorporate each of the preceding paragraphs 1-70 as if fully set forth herein.

ANSWER: Teva Pharms. incorporates its responses to the preceding paragraphs as if fully set forth herein.

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

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

73. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

74. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

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

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms.'s July 3, 2025 Notice Letter speaks for itself. Teva Pharms. denies any remaining allegations in this paragraph.

76. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

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

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

78. 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.

ANSWER: Teva Pharms. admits that Teva Pharms. sent a July 3, 2025 Notice Letter to Plaintiffs stating that Teva Pharms. submitted ANDA No. 220379 with the FDA to obtain approval to engage in the commercial manufacture, use, or sale of Teva Pharms.'s Proposed ANDA Products. Teva Pharms.'s July 3, 2025 Notice Letter speaks for itself. Teva Pharms. denies any remaining allegations in this paragraph.

79. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

80. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

81. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

RESPONSE TO COUNT III
(Infringement of U.S. Patent No. 11,951,111 under 35 U.S.C. § 271 by Defendants)

82. Plaintiffs incorporate each of the preceding paragraphs 1-81 as if fully set forth herein.

ANSWER: Teva Pharms. incorporates its responses to the preceding paragraphs as if fully set forth herein.

83. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

84. 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.

ANSWER: Teva Pharms. admits that Teva Pharms. submitted ANDA No. 220379 with the FDA to obtain approval to engage in the commercial manufacture, use, or sale of Teva Pharms.'s Proposed ANDA Products.

85. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

86. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

87. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

88. 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 noninfringing use.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

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

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms.'s July 3, 2025 Notice Letter speaks for itself. Teva Pharms. denies any remaining allegations in this paragraph.

90. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

RESPONSE TO COUNT IV
(Declaratory Judgment of Infringement of U.S. Patent No. 11,951,111 by Defendants)

91. Plaintiffs incorporate each of the preceding paragraphs 1-90 as if fully set forth herein.

ANSWER: Teva Pharms. incorporates its responses to the preceding paragraphs as if fully set forth herein.

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

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

93. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

94. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

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

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms.'s July 3, 2025 Notice Letter speaks for itself. Teva Pharms. denies any remaining allegations in this paragraph.

96. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

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

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

98. 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.

ANSWER: Teva Pharms. admits that Teva Pharms. sent a Notice Letter to Plaintiffs on July 3, 2025 stating that Teva Pharms. submitted ANDA No. 220379 with the FDA to obtain approval to engage in the commercial manufacture, use, or sale of Teva Pharms.'s Proposed ANDA Products. Teva Pharms.'s July 3, 2025 Notice Letter speaks for itself. Teva Pharms. denies any remaining allegations in this paragraph.

99. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

100. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

101. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

RESPONSE TO COUNT V
(Infringement of U.S. Patent No. 12,290,474 Under 35 U.S.C § 271 by Defendants)

102. Plaintiffs incorporate each of the preceding paragraphs 1-101 as if fully set forth herein.

ANSWER: Teva Pharms. incorporates its responses to the preceding paragraphs as if fully set forth herein.

103. Defendants' submission of ANDA No. 220379 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 '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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

104. 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. 220379.

ANSWER: Teva Pharms. has not submitted a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '474 Patent in connection with Teva Pharms.'s submission of ANDA No. 220379. Teva Pharms. denies any remaining allegations contained in this paragraph.

105. 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.

ANSWER: Teva Pharms. admits that Teva Pharms. submitted ANDA No. 220379 with the FDA to obtain approval to engage in the commercial manufacture, use, or sale of Teva Pharms.'s Proposed ANDA Products. Teva Pharms. denies any remaining allegations in this paragraph.

106. After final FDA approval of ANDA No. 220379, 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 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 '474 Patent and any additional periods of exclusivity.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

107. Defendants know, or should know, and intend that healthcare providers will prescribe, and patients will take, Teva's ANDA Products, and therefore will infringe at least one claim of the '474 Patent.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

108. Defendants know or should know that they will induce direct infringement of at least one claim of the '474 Patent, either literally or under the doctrine of equivalents.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

109. 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 noninfringing use.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. admits that the '474 Patent has been listed in the Orange Book with respect to LYBALVI®. Plaintiffs caused the '474 Patent to be listed in the Orange Book, and Teva denies that the '474 Patent was properly listed. Teva Pharms. denies any remaining allegations in this paragraph.

111. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

RESPONSE TO COUNT VI
(Declaratory Judgment of Infringement of U.S. Patent No. 12,390,474 by Defendants)

112. Plaintiffs incorporate each of the preceding paragraphs 1-111 as if fully set forth herein.

ANSWER: Teva Pharms. incorporates its responses to the preceding paragraphs as if fully set forth herein.

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

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

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

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

115. 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. 220379 is approved by marketing Teva's ANDA Product and encouraging doctors and patients to infringe the '474 Patent, unless enjoined by the Court.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

116. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. admits that the '474 Patent is listed in the Orange Book with respect to LYBALVI®. Plaintiffs caused the '474 Patent to be listed in the Orange Book,

and Teva Pharms. denies that the '474 Patent was properly listed. Teva Pharms. denies any remaining allegations contained in this paragraph.

117. 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) 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 '474 Patent, and Teva's ANDA Product is not suitable for substantial noninfringing use.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

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

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

119. 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 '474 Patent.

ANSWER: Teva Pharms. admits that Teva Pharms. sent a Notice Letter to Plaintiffs on July 3, 2025 stating that Teva Pharms. submitted ANDA No. 220379 with the FDA to obtain approval to engage in the commercial manufacture, use, or sale of Teva Pharms.'s Proposed ANDA Products. Teva Pharms.'s July 3, 2025 Notice Letter speaks for itself. Teva Pharms. denies any remaining allegations in this paragraph.

120. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

121. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

122. 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.

ANSWER: This Paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Teva Pharms. denies the allegations contained in this paragraph.

RESPONSE TO PRAYER FOR RELIEF

The remainder of the First Amended Complaint for Infringement (D.I. 5) is a prayer for relief and does not require a response. To the extent any response is required, Teva Pharms. denies that Plaintiffs are entitled to any relief whatsoever against Teva Pharms. in this action, either as prayed for in the First Amended Complaint or otherwise.

AFFIRMATIVE DEFENSES

Teva Pharms. asserts the following defenses in response to the allegations in the First Amended Complaint. Teva Pharms. expressly reserves the right to assert any other defenses that may now exist or in the future may be available based on the discovery and further factual investigation in this case. Assertion of a defense is not a concession that Teva Pharms. has the burden of proving the matter asserted.

FIRST AFFIRMATIVE DEFENSE
(Non-Infringement of the '466 Patent)

Teva Pharms. has not infringed, is not infringing, and will not infringe, literally or under the doctrine of equivalents, either directly or by contribution or inducement, any valid and enforceable claim of the '466 patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity, Unenforceability of the '466 Patent)

The claims of the ’466 patent are invalid and/or unenforceable for failing to comply with one or more requisite statutory and decisional requirements and/or conditions for patentability under Title 35 of the United States Code, including without limitation §§ 101, 102, 103, and/or 112.

THIRD AFFIRMATIVE DEFENSE
(Non-Infringement of the ’111 Patent)

Teva Pharms. has not infringed, is not infringing, and will not infringe, literally or under the doctrine of equivalents, either directly or by contribution or inducement, any valid and enforceable claim of the ’111 patent.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity, Unenforceability of the ’111 Patent)

The claims of the ’111 patent are invalid and/or unenforceable for failing to comply with one or more requisite statutory and decisional requirements and/or conditions for patentability under Title 35 of the United States Code, including without limitation §§ 101, 102, 103, and/or 112.

FIFTH AFFIRMATIVE DEFENSE
(Non-Infringement of the ’474 Patent)

Teva Pharms. has not infringed, is not infringing, and will not infringe, literally or under the doctrine of equivalents, either directly or by contribution or inducement, any valid and enforceable claim of the ’474 patent.

SIXTH AFFIRMATIVE DEFENSE
(Invalidity, Unenforceability of the ’474 Patent)

The claims of the ’474 patent are invalid and/or unenforceable for failing to comply with one or more requisite statutory and decisional requirements and/or conditions for patentability under Title 35 of the United States Code, including without limitation §§ 101, 102, 103, and/or 112.

SEVENTH AFFIRMATIVE DEFENSE
(Costs)

Upon information and belief, Plaintiffs are barred under 35 U.S.C. § 288 from recovering costs in connection with this action.

EIGHTH AFFIRMATIVE DEFENSE
(Adequate Remedy at Law, No Injunctive Relief)

Plaintiffs are not entitled to injunctive relief at least because any alleged injury to Plaintiffs is not immediate or irreparable, Plaintiffs have an adequate remedy at law, and/or public policy concerns weigh against any injunctive relief.

NINTH AFFIRMATIVE DEFENSE
(Failure to State a Claim)

With respect to each purported claim for relief alleged in the Complaint, Plaintiffs fail to allege facts sufficient to state a claim against Teva Pharms. upon which relief may be granted.

TENTH AFFIRMATIVE DEFENSE
(Equitable Defenses)

Plaintiffs' claims, in whole or in part, are barred by equitable doctrines including, but not limited to, waiver, equitable estoppel, judicial estoppel, disclaimer, dedication/disclosure, acquiescence, patent misuse, and/or unclean hands.

ELEVENTH AFFIRMATIVE DEFENSE
(Additional Defenses)

Teva Pharms. reserves the right to add to or amend this list of Affirmative Defenses with additional defenses that discovery may yield.

COUNTERCLAIMS

Without admitting any of the allegations of Plaintiffs Alkermes, Inc. and Alkermes Pharma Ireland Limited (together, "Alkermes" or "Counterclaim Defendants"), other than those expressly admitted herein, and without prejudice to the right of Teva Pharmaceuticals, Inc. ("Teva Pharms." or

"Counterclaim Plaintiff") to plead additional Counterclaims as the facts of the matter warrant, Teva Pharms. hereby asserts the following Counterclaims against Alkermes.

NATURE OF THE ACTION

1. These Counterclaims seek a declaratory judgment that Abbreviated New Drug Application ("ANDA") No. 220379 seeking approval to engage in the commercial manufacture, use or sale of Olanzapine and Samidorphan Tablets, 5 mg/10 mg, 10 mg/10 mg, 15 mg/10 mg and 20 mg/10 mg ("Teva Pharms.'s Proposed ANDA Products") do not infringe any valid and enforceable claim of United States 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"); that Teva Pharms.'s manufacture, use, offer to sell, sale, and/or importation into the United States, of Teva Pharms.'s Proposed ANDA Products, will not infringe, either directly or indirectly, any valid and enforceable claim of the Patents-in-Suit, either literally or under the doctrine of equivalents; and that each and every claim of the Patents-in-Suit is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112.

THE PARTIES

2. Teva Pharms. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

3. Upon information and belief and based on the allegations in the First Amended Complaint, 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.

4. Upon information and belief and based on the allegations in the First Amended Complaint, 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.

JURISDICTION AND VENUE

5. This is a declaratory judgment action arising under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). The requested relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court has personal jurisdiction over Alkermes, Inc. and Alkermes Pharma Ireland Limited because each Alkermes Counterclaim Defendant has availed itself of the legal protections of the State of New Jersey by initiating and prosecuting this action, and by voluntarily submitting to and employing the jurisdiction of this Court as a plaintiff in this matter.

7. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Alkermes has filed suit in this case, and has voluntarily submitted to the jurisdiction of the Court in this matter.

FACTUAL BACKGROUND

8. According to the United States Food & Drug Administration ("FDA") publication entitled "Approved Drug Products and Therapeutic Equivalence Evaluations" (the "Orange Book"), Alkermes, Inc. holds approved New Drug Application ("NDA") No. 213378 for olanzapine and samidorphan L-malate under the brand name LYBALVI®.

9. NDA holders are required to disclose to the FDA the patent numbers of patents claiming the drug or method of using such drug for which the NDA is submitted. The FDA lists these patents in the Orange Book.

10. Upon information and belief, based on the allegations in the First Amended Complaint, Alkermes Pharma Ireland Limited purports to be the assignee of the Patents-in-Suit.

11. Upon information and belief, one or more of the Alkermes Counterclaim Defendants caused the Patents-in-Suit to be listed in the Orange Book as patents that purport to cover LYBALVI® or methods of using LYBALVI®.

12. Teva Pharms. submitted ANDA No. 220379 to the FDA, seeking approval to engage in the commercial manufacture, use or sale of Teva Pharms.'s Proposed ANDA Products prior to the expiration of the Patents-in-Suit.

13. On or around July 3, 2025, Teva Pharms. sent Alkermes, Inc. and Alkermes Pharma Ireland Limited a notice letter providing notice of Teva Pharms.'s Submission of ANDA No. 220379 to the FDA.

14. On or around August 15, 2025, Alkermes filed this lawsuit alleging that Teva Pharms. infringes the Patents-in-Suit.

COUNT 1
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,707,466)

15. Teva Pharms. realleges and incorporates by reference the allegations in Paragraphs 1-14 of these Counterclaims as fully set forth herein.

16. There is an actual, substantial, continuing, and justiciable controversy between Teva Pharms. and Alkermes regarding the invalidity of the '466 patent based on Alkermes' allegations in its First Amended Complaint that Teva Pharms. has infringed or will infringe the '466 patent.

17. Each and every claim of the '466 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103, and/or 112.

18. The claimed invention of the '466 patent was patented, described in a printed publication, in public use, on sale, or otherwise available to the public more than one year before

the effective filing date of the claimed invention, and not subject to any exception under 35 U.S.C. § 102(b)(1).

19. The ’466 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

20. The alleged invention of the ’466 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’466 patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’466 patent and would have had a reasonable expectation of success in doing so.

21. The subject matter claimed in the ’466 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

22. The ’466 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the full scope of the invention purported to be covered thereby.

23. The ’466 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required

by the statutes of the United States to demonstrate to a person skilled in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein.

24. The claims of the '466 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter which the named inventors regard as their invention, as required by 35 U.S.C. § 112.

25. Teva Pharms. is entitled to a judicial declaration that all claims of the '466 patent are invalid.

COUNT 2
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,707,466)

26. Teva realleges and incorporates by reference the allegations in Paragraphs 1-25 of these Counterclaims as if fully set forth herein.

27. There is an actual, substantial, continuing, and justiciable controversy between Teva Pharms. and Alkermes regarding whether Teva Pharms.'s submission of ANDA No. 220379, and/or Teva Pharms.'s manufacture, use, offer to sell, sale, and/or importation into the United States of Teva Pharms.'s Proposed ANDA Products has infringed, or will infringe any valid and enforceable claim of the '466 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

28. Teva Pharms. has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '466 patent either literally or under the doctrine of equivalents and is not liable for such infringement.

29. Teva Pharms. is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '466 patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of Teva

Pharms.'s Proposed ANDA Products, has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '466 patent.

COUNT 3
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,951,111)

30. Teva Pharms. realleges and incorporates by reference the allegations in Paragraphs 1-29 of these Counterclaims as fully set forth herein.

31. There is an actual, substantial, continuing, and justiciable controversy between Teva Pharms. and Alkermes regarding the invalidity of the '111 patent based on Alkermes' allegations in its First Amended Complaint that Teva Pharms. has infringed or will infringe the '111 patent.

32. Each and every claim of the '111 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103, and/or 112.

33. The claimed invention of the '111 patent was patented, described in a printed publication, in public use, on sale, or otherwise available to the public more than one year before the effective filing date of the claimed invention, and not subject to any exception under 35 U.S.C. § 102(b)(1).

34. The '111 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

35. The alleged invention of the '111 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '111 patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been

motivated to combine the teachings of the prior art to achieve the alleged invention of the '111 patent and would have had a reasonable expectation of success in doing so.

36. The subject matter claimed in the '111 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

37. The '111 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the full scope of the invention purported to be covered thereby.

38. The '111 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to demonstrate to a person skilled in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein.

39. The claims of the '111 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter which the named inventors regard as their invention, as required by 35 U.S.C. § 112.

40. Teva Pharms. is entitled to a judicial declaration that all claims of the '111 patent are invalid.

COUNT 4
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,951,111)

41. Teva realleges and incorporates by reference the allegations in Paragraphs 1-40 of these Counterclaims as if fully set forth herein.

42. There is an actual, substantial, continuing, and justiciable controversy between Teva Pharms. and Alkermes regarding whether Teva Pharms.'s submission of ANDA No. 220379, and/or Teva Pharms.'s manufacture, use, offer to sell, sale, and/or importation into the United States of Teva Pharms.'s Proposed ANDA Products has infringed, or will infringe any valid and enforceable claim of the '111 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

43. Teva Pharms. has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '111 patent either literally or under the doctrine of equivalents and is not liable for such infringement.

44. Teva Pharms. is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '111 patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of Teva Pharms.'s Proposed ANDA Products, has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '111 patent.

COUNT 5
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,390,474)

45. Teva Pharms. realleges and incorporates by reference the allegations in Paragraphs 1-44 of these Counterclaims as fully set forth herein.

46. There is an actual, substantial, continuing, and justiciable controversy between Teva Pharms. and Alkermes regarding the invalidity of the '474 patent based on Alkermes'

allegations in its First Amended Complaint that Teva Pharms. has infringed or will infringe the '474 patent.

47. Each and every claim of the '474 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103, and/or 112.

48. The claimed invention of the '474 patent was patented, described in a printed publication, in public use, on sale, or otherwise available to the public more than one year before the effective filing date of the claimed invention, and not subject to any exception under 35 U.S.C. § 102(b)(1).

49. The '474 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

50. The alleged invention of the '474 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '474 patent is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '474 patent and would have had a reasonable expectation of success in doing so.

51. The subject matter claimed in the '474 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

52. The ’474 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the full scope of the invention purported to be covered thereby.

53. The ’474 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as required by the statutes of the United States to demonstrate to a person skilled in the art that the alleged inventors were in possession of the full scope of the subject matter of the claims contained therein.

54. The claims of the ’474 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter which the named inventors regard as their invention, as required by 35 U.S.C. § 112.

55. Teva Pharms. is entitled to a judicial declaration that all claims of the ’474 patent are invalid.

COUNT 6
(Declaratory Judgment of Noninfringement of U.S. Patent No. 12,390,474)

56. Teva Pharms. realleges and incorporates by reference the allegations in Paragraphs 1-55 of these Counterclaims as if fully set forth herein.

57. There is an actual, substantial, continuing, and justiciable controversy between Teva Pharms. and Alkermes regarding whether Teva Pharms.’s submission of ANDA No. 220379, and/or Teva Pharms.’s manufacture, use, offer to sell, sale, and/or importation into the United States of Teva Pharms.’s Proposed ANDA Products has infringed, or will infringe any valid and enforceable claim of the ’474 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

58. Teva Pharms. has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '474 patent either literally or under the doctrine of equivalents and is not liable for such infringement.

59. Teva Pharms. is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '474 patent either literally or under the doctrine of equivalents, and that the manufacture, use, sale, offer for sale, or importation of Teva Pharms.'s Proposed ANDA Products, has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '474 patent.

PRAYER FOR RELIEF

WHEREFORE, Teva Pharms. respectfully requests that this Court enter judgment against Alkermes and issue an order:

a) Dismissing Alkermes' First Amended Complaint with prejudice and denying each request for relief made by Alkermes therein;

b) Declaring all claims of the Patents-in-Suit invalid and/or unenforceable;

c) Declaring that the filing of the ANDA No. 220379 has not infringed and does not infringe any valid and enforceable claim of the Patents-in-Suit, either literally or under the doctrine of equivalents;

d) Declaring that Teva Pharms. has not directly or indirectly infringed, induced infringement of, or contributed to the infringement of any valid and enforceable claim of the Patents-in-Suit, either literally or under the doctrine of equivalents;

e) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Teva Pharms.'s Proposed ANDA Products does not, and would not, if marketed, directly or indirectly infringe any valid and enforceable claim, if any, of the Patents-in-Suit, either literally or under the doctrine of equivalents;

f) Declaring Teva Pharms. the prevailing party and awarding costs and attorney fees to Teva Pharms.;

g) Declaring that this case is an exceptional case in favor of Teva Pharms. pursuant to 35 U.S.C. § 285; and

h) Awarding Teva Pharms. such other and further relief as the Court deems just and proper.

Dated: October 24, 2025

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Attorneys for Defendant Teva Pharmaceuticals, Inc.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2 and 40.1

Defendant Teva Pharmaceuticals, Inc., by its undersigned counsel, hereby certifies that the matter in controversy is not subject to any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: October 24, 2025

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendant Teva Pharmaceuticals, Inc., by its undersigned counsel, hereby certifies that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: October 24, 2025

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