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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. APOTEX CORP. and APOTEX INC., Defendants.	Civil Action No. 1:25-cv-14977-KMW-AMD

DEFENDANTS APOTEX CORP. AND APOTEX INC.'S
ANSWER AND SEPARATE DEFENSES TO PLAINTIFFS' COMPLAINT

Defendants Apotex Corp. and Apotex Inc. (collectively, "Apotex" or "Defendants"), by and through their undersigned counsel, file this Answer and Separate Defenses to Plaintiffs Alkermes, Inc. and Alkermes Pharma Ireland Limited's (collectively, "Alkermes" or "Plaintiffs") Complaint, and state as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Apotex denies all allegations and characterizations in Plaintiffs' Complaint except those specifically admitted below. Apotex further denies liability for all allegations of patent liability and that Plaintiffs are entitled to the relief requested or any other.

In responding to the Complaint, Apotex uses the headings employed by Plaintiffs strictly as a convenience to the Court, and does not admit any allegation made in, or inference suggested by, such headings. Apotex answers the numbered paragraphs of Plaintiffs' Complaint as follows:

PARTIES

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

ANSWER: Paragraph 1 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, on information and belief, Apotex admits that Plaintiff Alkermes, Inc. is an entity organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 900 Winter Street, Waltham, Massachusetts 02451. Except as expressly admitted, Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 1, and on that basis denies these allegations.

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

ANSWER: Paragraph 2 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") lists Alkermes, Inc. as the holder of New Drug Application ("NDA") No. 213378 for LYBALVI®. Except as expressly admitted, Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 2, and on that basis denies these allegations.

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.

ANSWER: Paragraph 3 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, on information and belief, Apotex admits that

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. Except as expressly admitted, Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 3, and on that basis denies these allegations.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Paragraph 6 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 6.

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

ANSWER: Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 7.

8. Upon information and belief, Apotex Inc. and Apotex Corp. are agents of each other and/or operate in concert as integrated parts of the same business group.

ANSWER: Paragraph 8 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 8.

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

ANSWER: Admitted.

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

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 10.

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

ANSWER: Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 11.

NATURE OF THE ACTION

12. This is a civil action for patent infringement of U.S. Patent Nos. 11,707,466 (the "'466 Patent"), 11,951,111 (the "'111 Patent"), and 12,390,474 (the "'474 Patent") (collectively, "the Patents-in-Suit") arising under the United States Patent Laws, Title 35, United States Code, § 1, *et seq.*, and in particular under 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. § 2201-02.

ANSWER: Apotex admits that Plaintiffs filed this civil action alleging patent infringement under the patent laws of the United States, Title 35 of the United States Code, 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"). Except as expressly admitted, Apotex denies the allegations of Paragraph 12.

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

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that it filed its ANDA No. 220455

(Apotex's ANDA) with the FDA, and that Apotex seeks regulatory approval from the FDA for its ANDA. The content of Apotex's ANDA speaks for itself. Except as expressly admitted, Apotex denies the allegations of Paragraph 13.

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

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 14.

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

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 15.

JURISDICTION AND VENUE

> 16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and/or 35 U.S.C. § 271. This Court may declare the rights and other legal relations of the parties under 28 U.S.C. §§ 2201-02 because this action is an actual controversy within the Court's jurisdiction.

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex does not contest subject matter jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Apotex denies the allegations of Paragraph 16.

> 17. Defendants have committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Alkermes. Alkermes manufactures LYBALVI® for sale and use throughout the United States, including in New Jersey. Upon information and belief and as indicated in Apotex's Notice Letter, Defendants

prepared and filed ANDA No. 220455 with the intention of seeking to market Apotex's ANDA Product nationwide, including in New Jersey.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 17.

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

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 18.

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

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 19.

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

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Apotex denies the allegations of Paragraph 20.

21. This Court has personal jurisdiction over Apotex Inc. because, *inter alia*, Apotex Inc.: (1) has purposely availed itself of the privilege of doing business in New Jersey directly or indirectly through its subsidiary, agent, and/or alter ego; (2) upon information and belief, maintains pervasive, continuous, and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey; (3) upon information and

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

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Apotex denies the allegations of Paragraph 21.

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

ANSWER: Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Apotex denies the allegations of Paragraph 22.

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

ANSWER: Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex does not contest personal jurisdiction in this Court for the limited purposes of this action only. Prior consent to personal jurisdiction in this

Court has no bearing on this action. Except as expressly admitted, Apotex denies the allegations of Paragraph 23.

> 24. This Court has personal jurisdiction over Apotex Corp. because, *inter alia*, Apotex Corp.: (1) has purposely availed itself of the privilege of doing business in New Jersey, including, *inter alia*, by registering with the State of New Jersey's Department of Health as a wholesaler under Registration No. 5003192; (2) imports generic versions of branded pharmaceutical products for sale and use throughout the United States, including in the State of New Jersey; (3) markets, distributes, and sells generic versions of branded pharmaceutical products throughout the United States, including in the State of New Jersey; and (5) upon information and belief, derives substantial revenue from the sale of its products in New Jersey.

ANSWER: Paragraph 24 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Apotex denies the allegations of Paragraph 24.

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

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Apotex denies the allegations of Paragraph 25.

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

ANSWER: Paragraph 26 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex does not contest personal jurisdiction in this Court for the limited purposes of this action only. Prior consent to personal jurisdiction in this Court has no bearing on this action. Except as expressly admitted, Apotex denies the allegations of Paragraph 26.

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

ANSWER: Paragraph 27 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex does not contest venue in this Court for the limited purposes of this action only. Except as expressly admitted, Apotex denies the allegations of Paragraph 27.

28. Venue is proper in this Court as to Apotex Corp. under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because Apotex Corp. has a regular and established place of business in New Jersey at least because, upon information and belief, they: (1) have, in concert with Apotex Inc., sought final approval from the FDA to market and sell Apotex's ANDA Product in New Jersey; (2) have engaged in regular and established business contacts with New Jersey by, among other things, marketing, making, shipping, using, offering to sell, or selling pharmaceutical products in New Jersey, and deriving substantial revenue from such activities; and (3) upon information and belief, Defendant Apotex Corp. is registered with the State of New Jersey's Department of Health as a wholesaler under Registration No. 5003192.

ANSWER: Paragraph 28 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex does not contest venue in this Court for the limited purposes of this action only. Except as expressly admitted, Apotex denies the allegations of Paragraph 28.

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

pharmaceutical products in New Jersey; and (3) deriving substantial revenue from such activities.

ANSWER: Paragraph 29 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 29.

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

ANSWER: Paragraph 30 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 30.

THE PATENTS-IN-SUIT

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

ANSWER: Apotex admits that the '466 Patent is titled "Immediate Release Multilayer Tablet," and that the '466 Patent was issued by the United States Patent and Trademark Office ("USPTO") on or about July 25, 2023. What appears to be an uncertified copy of the '466 Patent was attached to Plaintiffs' Complaint as Exhibit A. Except as expressly admitted, Apotex denies the allegations of Paragraph 31.

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

ANSWER: Apotex admits that, on information and belief, according to publicly available information, Alkermes Pharma Ireland Limited is the assignee of the '466 Patent. Except as expressly admitted, Apotex denies the allegations of Paragraph 32.

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

ANSWER: Paragraph 33 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, To the extent an answer is required, Apotex admits

that the Orange Book lists the expiration date of the '466 patent as November 12, 2041. Except as expressly admitted, Apotex denies the allegations of Paragraph 33.

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

ANSWER: Apotex admits that the '111 Patent is titled "Immediate Release Multilayer Tablet," and that the '111 Patent was issued by the USPTO on or about April 9, 2024. What appears to be an uncertified copy of the '111 Patent was attached to Plaintiffs' Complaint as Exhibit B. Except as expressly admitted, Apotex denies the allegations of Paragraph 34.

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

ANSWER: Apotex admits that, on information and belief, according to publicly available information, Alkermes Pharma Ireland Limited is the assignee of the '111 Patent. Except as expressly admitted, Apotex denies the allegations of Paragraph 35.

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

ANSWER: Paragraph 36 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that the Orange Book lists the expiration date of the '111 patent as November 12, 2041. Except as expressly admitted, Apotex denies the allegations of Paragraph 36.

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

ANSWER: Apotex admits that the '474 Patent is titled "Immediate Release Multilayer Tablet," and that the '474 Patent was issued by the USPTO on or about August 19, 2025. What appears to be an uncertified copy of the '474 Patent was attached to Plaintiffs' Complaint as Exhibit C. Except as expressly admitted, Apotex denies the allegations of Paragraph 34.

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

ANSWER: Apotex admits that, on information and belief, according to publicly available information, Alkermes Pharma Ireland Limited is the assignee of the '474 Patent. Except as expressly admitted, Apotex denies the allegations of Paragraph 38.

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

ANSWER: Paragraph 39 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that the Orange Book lists the expiration date of the '474 patent as November 12, 2041. Except as expressly admitted, Apotex denies the allegations of Paragraph 39.

ALKERMES' LYBALVI® PRODUCT

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

ANSWER: Paragraph 40 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 40.

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

ANSWER: Paragraph 41 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 41.

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

ANSWER: Paragraph 42 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 42.

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

ANSWER: Paragraph 43 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that the Orange Book lists Alkermes, Inc. as the holder of NDA No. 213378 for LYBALVI®. Except as expressly admitted, Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 43, and on that basis denies these allegations.

44. LYBALVI® is a combination product including two active pharmaceutical agents: an antipsychotic, olanzapine, and opioid receptor antagonist, samidorphan. Olanzapine is an atypical antipsychotic. Samidorphan helps counteract some of the metabolic side effects of olanzapine.

ANSWER: Paragraph 44 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 44, and on that basis denies these allegations.

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

ANSWER: Paragraph 45 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex lacks knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 45, and on that basis denies these allegations.

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

ANSWER: Apotex admits that the Orange Book lists the Patents-in-Suit in connection with NDA No. 213378 for LYBALVI®. Except as expressly admitted, Apotex denies the allegations of Paragraph 46.

APOTEX'S LYBALVI® PRODUCT

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

ANSWER: Paragraph 47 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that on or about July 14, 2025, Apotex sent a Notice Letter to Alkermes. The content of Apotex's Notice Letter speaks for itself. Except as expressly admitted, Apotex denies the allegations of Paragraph 47.

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

ANSWER: Paragraph 48 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Apotex's Notice Letter speaks for itself. Except as expressly admitted, Apotex denies the allegations of Paragraph 48.

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

ANSWER: Paragraph 49 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Apotex's ANDA speaks for itself. Except as expressly admitted, Apotex denies the allegations of Paragraph 49.

50. In the Notice Letter, Apotex stated that ANDA No. 220455 included a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '111 and '466 Patents. Apotex also contended that the '111 and '466

Patents will not be infringed by the commercial manufacture, use, or sale of Apotex's ANDA product.

ANSWER: Paragraph 50 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Apotex's Notice Letter speaks for itself. Except as expressly admitted, Apotex denies the allegations of Paragraph 50.

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

ANSWER: Paragraph 51 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Apotex's ANDA speaks for itself. Except as expressly admitted, Apotex denies the allegations of Paragraph 51.

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

ANSWER: Paragraph 52 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 52.

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

ANSWER: Paragraph 53 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 53.

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

ANSWER: Apotex admits that it produced the entirety of ANDA No. 220455, as filed with the FDA, to Alkermes pursuant to an Offer of Confidential Access. Except as expressly admitted, Apotex denies the allegations of Paragraph 54.

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

ANSWER: Paragraph 55 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 55.

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

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

ANSWER: Apotex incorporates each of its responses to Plaintiffs' preceding paragraphs 1-55 as if fully set forth herein.

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

ANSWER: Paragraph 57 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 57.

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

ANSWER: Paragraph 58 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 58.

59. After final FDA approval of ANDA No. 220455, Defendants will infringe one or more claims of the '466 Patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Apotex's ANDA Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any final FDA approval of ANDA No. 220455 shall be no earlier than the expiration of the '466 Patent and any additional periods of exclusivity.

ANSWER: Paragraph 59 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 59.

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

ANSWER: Paragraph 60 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 60.

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

ANSWER: Paragraph 61 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 61.

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

ANSWER: Paragraph 62 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 62.

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

ANSWER: Paragraph 63 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Apotex's Notice Letter speaks for itself. Except as expressly admitted, Apotex denies the allegations of Paragraph 63.

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

ANSWER: Paragraph 64 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 64.

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

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

ANSWER: Apotex incorporates each of its responses to Plaintiffs' preceding paragraphs 1-64 as if fully set forth herein.

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

ANSWER: Paragraph 66 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 66.

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

ANSWER: Paragraph 67 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 67.

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

ANSWER: Paragraph 68 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 68.

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

ANSWER: Paragraph 69 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Apotex's Notice Letter speaks for itself. Except as expressly admitted, Apotex denies the allegations of Paragraph 69.

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

ANSWER: Paragraph 70 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 70.

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

ANSWER: Paragraph 71 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 71.

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

ANSWER: Admitted.

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

ANSWER: Paragraph 73 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 73.

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

ANSWER: Paragraph 74 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 74.

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

ANSWER: Paragraph 75 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 75.

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

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

ANSWER: Apotex incorporates each of its responses to Plaintiffs' preceding paragraphs 1-75 as if fully set forth herein.

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

ANSWER: Paragraph 77 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 77.

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

ANSWER: Paragraph 78 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 78.

79. After final FDA approval of ANDA No. 220455, Defendants will infringe one or more claims of the '111 Patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Apotex's ANDA Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any final FDA approval of ANDA No. 220455 shall be no earlier than the expiration of the '111 Patent and any additional periods of exclusivity.

ANSWER: Paragraph 79 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 79.

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

ANSWER: Paragraph 80 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 80.

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

ANSWER: Paragraph 81 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 81.

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

ANSWER: Paragraph 82 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 82.

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

ANSWER: Paragraph 83 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Apotex's Notice Letter speaks for itself. Except as expressly admitted, Apotex denies the allegations of Paragraph 83.

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

ANSWER: Paragraph 84 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 84.

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

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

ANSWER: Apotex incorporates each of its responses to Plaintiffs' preceding paragraphs 1-84 as if fully set forth herein.

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

ANSWER: Paragraph 86 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 86.

87. Upon information and belief, upon final FDA approval of ANDA No. 220455, Defendants intend to, and will, infringe one or more claims of the '111 Patent, under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents by the manufacture, use, sale, or importation of Apotex's ANDA Product, unless enjoined by the Court.

ANSWER: Paragraph 87 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 87.

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

ANSWER: Paragraph 88 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 88.

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

ANSWER: Paragraph 89 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Apotex's Notice Letter speaks for itself. Except as expressly admitted, Apotex denies the allegations of Paragraph 89.

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

ANSWER: Paragraph 90 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 90.

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

ANSWER: Paragraph 91 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 91.

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

ANSWER: Admitted.

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

ANSWER: Paragraph 93 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 93.

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

ANSWER: Paragraph 94 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 94.

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

ANSWER: Paragraph 95 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 95.

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

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

ANSWER: Apotex incorporates each of its responses to Plaintiffs' preceding paragraphs 1-95 as if fully set forth herein.

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

ANSWER: Paragraph 97 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 97.

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

ANSWER: Paragraph 98 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 98.

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

ANSWER: Paragraph 99 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 99.

100. After final FDA approval of ANDA No. 220455, Defendants will infringe one or more claims of the '474 Patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Apotex's ANDA Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any final FDA approval of ANDA No. 220455 shall be no earlier than the expiration of the '474 Patent and any additional periods of exclusivity.

ANSWER: Paragraph 100 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 100.

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

ANSWER: Paragraph 101 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 101.

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

ANSWER: Paragraph 102 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 102.

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

ANSWER: Paragraph 103 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 103.

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

ANSWER: Paragraph 104 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 104.

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

ANSWER: Paragraph 105 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 105.

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

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

ANSWER: Apotex incorporates each of its responses to Plaintiffs' preceding paragraphs 1-105 as if fully set forth herein.

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

ANSWER: Paragraph 107 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 107.

108. Upon information and belief, upon final FDA approval of ANDA No. 220455, Defendants intend to, and will, infringe one or more claims of the '474 Patent, under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents by the manufacture, use, sale, or importation of Apotex's ANDA Product, unless enjoined by the Court.

ANSWER: Paragraph 108 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 108.

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

ANSWER: Paragraph 109 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 109.

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

ANSWER: Paragraph 110 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 110.

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

ANSWER: Paragraph 111 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 111.

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

ANSWER: Paragraph 112 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 112.

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

ANSWER: Paragraph 113 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 113.

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

ANSWER: Paragraph 114 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 114.

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

ANSWER: Paragraph 115 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 115.

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

ANSWER: Paragraph 116 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 116.

PLAINTIFFS' PRAYER FOR RELIEF

All allegations in Plaintiffs' Complaint that are not expressly admitted by Apotex are denied. Apotex denies that Plaintiffs are entitled to any of the relief sought in their Prayer for Relief.

APOTEX'S SEPARATE DEFENSES

Without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not expressly admitted, Apotex asserts the following Separate Defenses to Plaintiffs' Complaint without assuming the burden of proof on any defense that would otherwise rest on Plaintiffs. Apotex reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery.

FIRST SEPARATE DEFENSE
(No Infringement of U.S. Patent No. 11,707,466)

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Apotex's ANDA No. 220455 has not infringed, do not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the '466 patent.

SECOND SEPARATE DEFENSE
(Invalidity of U.S. Patent No. 11,707,466)

The '466 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101 *et seq*. including, *inter alia*, §§ 102, 103, and/or 112, or under judicially-created bases for invalidation, including but not limited to, obviousness-type double patenting.

THIRD SEPARATE DEFENSE
(No Infringement of U.S. Patent No. 11,951,111)

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Apotex's ANDA No. 220455 has not infringed, do not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the '111 patent.

FOURTH SEPARATE DEFENSE
(Invalidity of U.S. Patent No. 11,951,111)

The '111 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101 *et seq*. including, *inter alia*, §§ 102, 103, and/or 112, or under judicially-created bases for invalidation, including but not limited to, obviousness-type double patenting.

FIFTH SEPARATE DEFENSE
(No Infringement of U.S. Patent No. 12,390,474)

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Apotex's ANDA No. 220455 has not infringed, do not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the '474 patent.

SIXTH SEPARATE DEFENSE
(Invalidity of U.S. Patent No. 12,390,474)

The '474 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101 *et seq*. including, *inter alia*, §§ 102, 103, and/or 112, or under judicially-created bases for invalidation, including but not limited to, obviousness-type double patenting.

SEVENTH SEPARATE DEFENSE
(Failure to State a Claim for Exceptional Case)

Plaintiffs' Complaint fails to state a claim for exceptional case under 35 U.S.C. § 285. Apotex's actions in defending this case do not give rise to an exceptional case.

RESERVATION OF DEFENSES

Apotex reserves any and all defenses available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

Dated: October 27, 2025

Respectfully submitted,

s/ Kaan Ekiner

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CERTIFICATE PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: October 27, 2025

s/ Kaan Ekiner
Kaan Ekiner

CERTIFICATE OF SERVICE

I hereby certify that on October 27, 2025, a true and correct copy of the foregoing **DEFENDANTS APOTEX CORP. AND APOTEX INC.'S ANSWER AND SEPARATE DEFENSES TO PLAINTIFFS' COMPLAINT** was filed electronically with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

s/ Kaan Ekiner
Kaan Ekiner