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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ALKERMES, INC. and ALKERMES PHARMA IRELAND LIMITED, Plaintiffs, v. MSN PHARMACEUTICALS, INC. and MSN LABORATORIES PRIVATE LIMITED, Defendants.	C.A. No. 1:25-cv-15324-KMW-AMD (FILED ELECTRONICALLY)

DEFENDANT MSN PHARMACEUTICALS, INC. AND MSN LABORATORIES PRIVATE LIMITED'S ANSWER, DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT

Defendants MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited (together, "MSN" or "Defendants") hereby file their Answer, Defenses, and Counterclaims in response to the Complaint for Patent Infringement ("Complaint") filed on September 5, 2025, by Plaintiffs Alkermes, Inc. and Alkermes Pharma Ireland Limited (together, "Alkermes" or "Plaintiffs"),

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:

MSN lacks knowledge or information sufficient to form a belief about the truth of the allegations in 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 to which no response is required. To the extent a response is required, MSN admits that the U.S. Food and Drug Administration's ("FDA") website lists Alkermes, Inc. as the holder of New Drug Application ("NDA") No. 213378. MSN denies any remaining allegations of 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.

ANSWER:

MSN lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 3 and on that basis denies these allegations.

4. Upon information and belief, Defendant MSN Pharmaceuticals, Inc. is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at 20 Duke Road, Piscataway, New Jersey 00854.

ANSWER:

MSN admits that MSN Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware and maintains a place of business at 20 Duke Road, Piscataway, New Jersey 08854. MSN denies the remaining allegations of Paragraph 4.

5. Upon information and belief, Defendant MSN Laboratories Private Limited is an entity organized and existing under the laws of the Republic of India, with a principal place of business at MSN House, Plot No. C-24, Industrial Estate, Sanath Nagar Industrial Estate, Sanath Nagar, Hyderabad, Telangana, 500018, India.

ANSWER:

MSN admits that MSN Laboratories Private Limited is an entity organized and existing under the laws of the Republic of India, with a place of business at MSN House, Plot No. C-24, Industrial Estate, Sanathnagar, Hyderabad, 500018, Telangana, India. MSN denies the remaining allegations of Paragraph 5.

6. Upon information and belief, Defendant Novadoz Pharmaceuticals LLC is an entity organized and existing under the laws of the State of New Jersey, with a principal place of business at 20 Duke Road, Piscataway, New Jersey 00854.

ANSWER:

All claims against Novadoz Pharmaceuticals LLC have been dismissed, and therefore no response is required as to allegations pertaining to Novadoz Pharmaceuticals LLC, and such allegations in this paragraph are therefore denied on that basis.

7. Upon information and belief, MSN Pharms. and Novadoz are wholly owned subsidiaries of MSN Labs.

ANSWER:

MSN admits that MSN Pharmaceuticals, Inc. is a wholly owned subsidiary of MSN Laboratories Private Limited. Further, all claims against Novadoz Pharmaceuticals LLC have been dismissed, and therefore no response is required as to allegations pertaining to Novadoz Pharmaceuticals LLC, and such allegations in this paragraph are therefore denied on that basis.

MSN denies the remaining allegations of Paragraph 7.

8. Upon information and belief, MSN Labs. directs or controls the operations, management, and activities of MSN Pharms. and Novadoz, including in the United States.

ANSWER:

Paragraph 8 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that MSN Pharmaceuticals, Inc. is a wholly owned subsidiary of MSN Laboratories Private Limited. Further, all claims against Novadoz Pharmaceuticals LLC have been dismissed, and therefore no response is required as to allegations pertaining to Novadoz Pharmaceuticals LLC, and such allegations in this paragraph are therefore denied on that basis. MSN denies the remaining allegations of Paragraph 8.

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

ANSWER:

Paragraph 9 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that MSN Pharmaceuticals, Inc. is a wholly owned subsidiary of MSN Laboratories Private Limited. Further, all claims against Novadoz Pharmaceuticals LLC have been dismissed, and therefore no response is required as to allegations pertaining to Novadoz Pharmaceuticals LLC, and such allegations in this paragraph are therefore denied on that basis. MSN denies the remaining allegations of Paragraph 9.

10. Upon information and belief, Defendant MSN Pharms. holds Abbreviated New Drug Application ("ANDA") No. 220726.

ANSWER:

MSN admits that MSN Laboratories Private Limited submitted Abbreviated New Drug Application ("ANDA") No. 220726 to the FDA. MSN denies the remaining allegations of Paragraph 10.

11. Upon information and belief, Defendants have been acting in concert with respect to the preparation and submission of ANDA No. 220726 and the development of MSN's proposed generic LYBALVI® product described therein ("MSN's ANDA Product").

ANSWER:

Paragraph 11 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that MSN Laboratories Private Limited submitted ANDA No. 220726 to the FDA seeking approval to market the olanzapine and samidorphan tablets described in ANDA No. 220726 ("MSN's ANDA Product") in the United States. MSN denies the remaining allegations of Paragraph 11.

12. Upon information and belief, following any final FDA approval of ANDA No. 220726, Defendants will market, distribute, sell, offer for sale, and/or import MSN's ANDA Product throughout the United States.

ANSWER:

Paragraph 12 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits that MSN Laboratories Private Limited submitted ANDA No. 220726 to the FDA seeking approval to market MSN's ANDA Product in the United States. MSN denies the remaining allegations of Paragraph 12.

NATURE OF THE ACTION

13. 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"), 8,778,960 (the "'960 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:

MSN admits that Plaintiffs' Complaint purports to state an action for infringement of U.S. Patent Nos. 11,707,466 ("'466 Patent"), 11,951,111 ("'111 Patent"), 8,778,960 ("'960 Patent"), and 12,390,474 ("'474 Patent") (collectively, "Patents-in-Suit") and that this action purports to arise under the patent laws of the United States, in particular under 35 U.S.C. § 271.

MSN denies the remaining allegations of Paragraph 13.

14. This action is based on Defendants' submission to the FDA of ANDA No. 220726, seeking approval to manufacture and sell a generic version of LYBALVI® prior to the expiration of the Patents-in-Suit, which are listed in Approved Drug Products with Therapeutic Equivalence Evaluations (an FDA publication commonly known as the "Orange Book") for LYBALVI®.

ANSWER:

Paragraph 14 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that Plaintiffs' Complaint purports to relate to ANDA No. 220726 submitted by MSN Laboratories Private Limited to the FDA seeking approval to market MSN's ANDA Product in the United States. MSN denies the remaining allegations of Paragraph 14.

15. 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. 220726 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 15 states legal conclusions to which no response is required. To the extent a response is required, denied.

16. 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 16 contains legal conclusions to which no response is required. To the extent a response is required, denied.

JURISDICTION AND VENUE

17. 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 17 contains legal conclusions to which no response is required. To the extent a response is required, MSN does not contest this Court's subject matter jurisdiction solely for the limited purposes of this action only and expressly reserves the right to contest subject matter jurisdiction in any other case as to any party, including Plaintiffs. MSN denies the remaining allegations of Paragraph 17.

18. 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 MSN's Notice Letter, Defendants prepared and filed ANDA No. 220726 with the intention of seeking to market MSN's ANDA Product nationwide, including in New Jersey.

ANSWER:

Paragraph 18 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that MSN Laboratories Private Limited submitted ANDA No. 220726 to the FDA seeking approval to market MSN's ANDA Product in the United States. MSN denies the remaining allegations of paragraph 18.

19. Upon information and belief, Defendants plan to sell MSN's ANDA Product in the State of New Jersey, list MSN's ANDA Product in the State of New Jersey's prescription drug formulary, and seek Medicaid reimbursements for sales of MSN'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 19 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that MSN Laboratories Private Limited submitted ANDA No. 220726 to the FDA seeking approval to market MSN's ANDA Product in the United States. MSN denies the remaining allegations of paragraph 19.

20. Upon information and belief, Defendants know and intend that MSN'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 MSN's ANDA Product.

ANSWER:

Paragraph 20 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that MSN Laboratories Private Limited submitted ANDA No. 220726 to the FDA seeking approval to market MSN's ANDA Product in the United States. MSN denies the remaining allegations of paragraph 20.

21. Upon information and belief, Defendants worked in concert to prepare ANDA No. 220726 in and file it from Piscataway, New Jersey, which constituted an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER:

Paragraph 21 contains legal conclusions to which no response is required. To the extent a response is required, denied.

22. 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 22 contains legal conclusions to which no response is required. To the extent a response is required, MSN does not contest this Court's personal jurisdiction over MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited solely for the limited purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. MSN denies the remaining allegations of paragraph 22.

23. This Court has personal jurisdiction over MSN Pharms. because, *inter alia*, MSN Pharms. (1) has a principal place of business in New Jersey at 20 Duke Road, Piscataway, New Jersey 00854; (2) 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. 5006107 and by registering with the New Jersey

Department of the Treasury in Piscataway, NJ under Entity Identification No. 0400627791; (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 23 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that MSN Pharmaceuticals, Inc. is in the business of developing, marketing, importing and selling pharmaceutical products, including generic drug products. MSN admits that MSN Pharmaceuticals, Inc. has conducted and continues to conduct business in New Jersey, and that MSN Pharmaceuticals, Inc. has a place of business at 20 Duke Rd., Piscataway, New Jersey 08854. In addition, MSN does not contest this Court's personal jurisdiction over MSN Pharmaceuticals, Inc. solely for the limited purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. MSN denies the remaining allegations of Paragraph 23.

24. This Court also has personal jurisdiction over MSN Pharms. because, *inter alia*, MSN 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 24 contains legal conclusions to which no response is required. MSN denies the remaining allegations of Paragraph 24.

25. This Court also has personal jurisdiction over Defendant MSN 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 the purposes of those actions, and has asserted counterclaims in those actions, including in at least *Janssen Prods., L.P. v. MSN Pharms. Inc*., No. 21-cv-14622 (D.N.J.); *Bausch Health Ireland Limited, et al. v. MSN Laboratories Private Limited, et al.*, No. 24-cv-11179 (D.N.J.); *BeiGene USA, Inc. et al. v. MSN Pharmaceuticals Inc., et al*., No. 24-cv-01971 (D.N.J.).

ANSWER:

Paragraph 25 contains legal conclusions to which no response is required. To the extent a response is required, MSN does not contest this Court's personal jurisdiction over MSN Pharmaceuticals, Inc. solely for the limited purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiffs. MSN further admits that MSN Pharmaceuticals, Inc. was a party before this Court in the civil actions listed in Paragraph 25, and states that the filings in those cases speak for themselves. MSN denies the remaining allegations of Paragraph 25.

26. This Court has personal jurisdiction over MSN Labs. because, *inter alia*, MSN Labs.: (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 MSN's ANDA Product in New Jersey.

ANSWER:

Paragraph 26 states a legal conclusion to which no response is required. To the extent a response is required, MSN admit MSN Laboratories Private Limited is in the business of, *inter alia*, developing, manufacturing, and selling pharmaceutical products, including generic drug products. MSN also does not contest jurisdiction in this Court solely for purposes of the claims asserted against MSN Laboratories Private Limited in this case. MSN denies the remaining allegations of Paragraph 26.

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

satisfies due process.

ANSWER:

Paragraph 27 states legal conclusions to which no response is required. To the extent a response is required, MSN does not contest jurisdiction in this Court solely for purposes of the claims asserted against MSN Laboratories Private Limited in this case. MSN denies the remaining allegations of Paragraph 27.

28. This Court also has personal jurisdiction over Defendant MSN Labs. 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 *Vifor (International) AG, et al. v. MSN Laboratories Private Limited, et al.*, No. 25-cv-3286 (D.N.J.); *Bausch Health Ireland Limited, et al. v. MSN Laboratories Private Limited, et al.*, No. 24-cv-11179 (D.N.J.); *Intra-Cellular Therapies, Inc. v. MSN Laboratories Private Limited*, No. 24-cv-10238 (D.N.J.).

ANSWER:

Paragraph 28 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that MSN Laboratories Private Limited was a party before this Court in the civil actions listed in Paragraph 28, and states that the filings in those cases speak for themselves. In addition, MSN does not contest this Court's personal jurisdiction over MSN Laboratories Private Limited solely for the limited purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiff. MSN denies the remaining allegations of Paragraph 28.

29. This Court has personal jurisdiction over Novadoz because, *inter alia*, Novadoz: (1) has a principal place of business in New Jersey at 20 Duke Road, Piscataway, New Jersey 00854; (2) 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. 5005442 and by *registering* with the New Jersey Department of the Treasury in Piscataway, NJ under Entity Identification No. 0450229624; (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:

All claims against Novadoz Pharmaceuticals LLC have been dismissed, and therefore no response is required as to allegations pertaining to Novadoz Pharmaceuticals LLC, and such allegations in this paragraph are therefore denied on that basis.

30. This Court also has personal jurisdiction over Novadoz because, *inter alia*, Novadoz 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:

All claims against Novadoz Pharmaceuticals LLC have been dismissed, and therefore no response is required as to allegations pertaining to Novadoz Pharmaceuticals LLC, and such allegations in this paragraph are therefore denied on that basis.

31. This Court also has personal jurisdiction over Defendant Novadoz 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, including in at least *Novartis AG, et al. v. Novadoz Pharmaceuticals LLC, et al.*, No. 25-cv-849 (D.N.J.).

ANSWER:

All claims against Novadoz Pharmaceuticals LLC have been dismissed, and therefore no response is required as to allegations pertaining to Novadoz Pharmaceuticals LLC, and such allegations in this paragraph are therefore denied on that basis.

32. Venue is proper in this Court as to MSN Pharms. under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because, upon information and belief, MSN 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 32 states a legal conclusion to which no response is required. To the extent a response is required, MSN Pharmaceuticals, Inc. does not contest the venue in this Court solely for the purposes of the claims in this case. MSN admits that MSN Pharmaceuticals, Inc. operates

a place of business in this judicial district. MSN denies any remaining allegations of paragraph 32.

33. Venue is also proper in this Court as to MSN Pharms. under 28 U.S.C. §§ 1391 and 1400(b), because MSN Pharms. is registered with the State of the State of New Jersey's Department of Health as a wholesaler under Registration No. 5006107 and with the New Jersey Department of the Treasury in Piscataway, NJ under Entity Identification No. 0400627791.

ANSWER:

Paragraph 33 contains legal conclusions to which no response is required. For purposes of this action only, MSN does not contest that venue is proper as to MSN Pharmaceuticals, Inc. To the extent that a response is required, MSN denies the remaining allegations in paragraph 33.

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

ANSWER:

Paragraph 34 contains legal conclusions to which no response is required. For purposes of this action only, MSN does not contest that venue is proper as to MSN Laboratories Private Limited. To the extent that a response is required, MSN denies the remaining allegations in paragraph 34.

35. Venue is proper in this Court as to Novadoz under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because, upon information and belief, Novadoz 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:

All claims against Novadoz Pharmaceuticals LLC have been dismissed, and therefore no response is required as to allegations pertaining to Novadoz Pharmaceuticals LLC, and such allegations in this paragraph are therefore denied on that basis.

36. Venue is also proper in this Court as to Nozadoz [sic] under 28 U.S.C. §§ 1391 and 1400(b), because Novadoz is registered with the State of New Jersey's Department of Health as a wholesaler under Registration No. 5005442 and with the New Jersey Department

of the Treasury in Piscataway, NJ under Entity Identification No. 0450229624.

ANSWER:

All claims against Novadoz Pharmaceuticals LLC have been dismissed, and therefore no response is required as to allegations pertaining to Novadoz Pharmaceuticals LLC, and such allegations in this paragraph are therefore denied on that basis.

37. Upon information and belief, Defendants: (1) have sought approval from the FDA to market and sell MSN'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 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, MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. do not contest venue or jurisdiction in this judicial district for purposes of this action. MSN denies any remaining allegations contained in this paragraph, including because all claims against Novadoz Pharmaceuticals LLC have been dismissed.

38. 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 MSN's ANDA Product.

ANSWER:

Paragraph 38 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, MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. do not contest venue or jurisdiction in this judicial district for purposes of this action. MSN denies any remaining allegations contained in this paragraph, including because all claims against Novadoz Pharmaceuticals LLC

have been dismissed.

THE PATENTS-IN-SUIT

39. 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:

Paragraph 39 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that Exhibit A of Plaintiffs' Complaint purports to be a copy of the '466 Patent. MSN further admits that the face of the '466 Patent states that it issued on July 25, 2023. MSN further admits that, on its face, the '466 Patent is titled "Immediate Release Multilayer Tablet." MSN denies the remaining allegations of Paragraph 39.

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

ANSWER:

Paragraph 40 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that the online records of the U.S. Patent and Trademark Office ("USPTO") lists Alkermes Pharma Ireland Limited as the assignee of the '466 Patent. MSN lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 40 and on that basis denies these allegations

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

ANSWER:

Paragraph 41 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") lists November 12, 2041 as the expiration date of the '466 Patent. MSN lacks knowledge or information sufficient to form a

belief about the truth of the remaining allegations in Paragraph 41 and on that basis denies these allegations.

42. 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:

Paragraph 42 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that Exhibit B of Plaintiffs' Complaint purports to be a copy of the '111 Patent. MSN further admits that the face of the '111 Patent states that it issued on April 9, 2024. MSN further admits that, on its face, the '111 Patent is titled "Immediate Release Multilayer Tablet." MSN denies the remaining allegations of Paragraph 42.

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

ANSWER:

Paragraph 43 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that the online records of the USPTO list Alkermes Pharma Ireland Limited as the assignee of the '111 Patent. MSN lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 43 and on that basis denies these allegations.

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

Paragraph 44 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that the FDA's Orange Book lists November 12, 2041 as the expiration date of the '111 Patent. MSN lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 44 and on that basis denies these allegations.

45. U.S. Patent No. 8,778,960, entitled "Methods for Treating Antipsychotic-Induced Weight Gain," was duly and legally issued on July 15, 2014. A true and correct copy of the '960 Patent is attached hereto as "Exhibit C."

ANSWER:

Paragraph 45 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that Exhibit C of Plaintiffs' Complaint purports to be a copy of the '960 Patent. MSN further admits that the face of the '960 Patent states that it issued on July 15, 2014. MSN further admits that, on its face, the '960 Patent is titled "Methods for Treating Antipsychotic-Induced Weight Gain." MSN denies the remaining allegations of Paragraph 45.

46. Alkermes Pharma Ireland Limited is the assignee of, and holds all rights, title, and interest in, the '960 Patent.

ANSWER:

Paragraph 46 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that the online records of the USPTO list Alkermes Pharma Ireland Limited as the assignee of the '960 Patent. MSN lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 46 and on that basis denies these allegations.

47. The '960 Patent currently expires on February 13, 2032.

ANSWER:

Paragraph 47 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that the FDA's Orange Book lists February 13, 2032 as the expiration date of the '960 Patent. MSN lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 47 and on that basis denies these allegations.

48. 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 D."

ANSWER:

Paragraph 48 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that Exhibit D of Plaintiffs' Complaint purports to be a copy of the '474 Patent. MSN further admits that the face of the '474 Patent states that it issued on August 19, 2025. MSN further admits that, on its face, the '474 Patent is titled "Immediate Release Multilayer Tablet." MSN denies the remaining allegations of Paragraph 48.

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

ANSWER:

Paragraph 49 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that the online records of the USPTO list Alkermes Pharma Ireland Limited as the assignee of the '474 Patent. MSN lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 49 and on that basis denies these allegations.

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

ANSWER:

Paragraph 50 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that the FDA's Orange Book lists November 12, 2041 as the expiration date of the '474 Patent. MSN lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 50 and on that basis denies these allegations.

ALKERMES' LYBALVI® PRODUCT

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

ANSWER:

MSN lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 51 and on that basis denies these allegations.

52. 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:

MSN lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 52 and on that basis denies these allegations.

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

ANSWER:

MSN lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 53 and on that basis denies these allegations.

54. 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 54 contains legal conclusions to which no response is required. To the extent that a response is required, MSN admits that the FDA's website lists Alkermes Inc. as the holder of NDA No. 213378 and an initial approval date of May 28, 2021. MSN lacks knowledge or

information sufficient to form a belief about the truth of the remaining allegations in Paragraph 54 and on that basis denies these allegations.

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

ANSWER:

MSN admits that the package insert for LYBALVI® dated 02/28/2025, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/213378s008lbl.pdf, states the following:

---------- **INDICATIONS AND USAGE**----------

LYBALVI is a combination of olanzapine, an atypical antipsychotic, and samidorphan, an opioid antagonist, indicated for the treatment of:

- Schizophrenia in adults (1)
- Bipolar I disorder in adults (1)
  - Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate
  - Maintenance monotherapy treatment

MSN lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 55 and on that basis denies these allegations.

56. 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:

MSN admits that the package insert for LYBALVI® dated 02/28/2025, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/213378s008lbl.pdf, states the following:

---------- **DOSAGE FORMS AND STRENGTHS**----------

Tablets (olanzapine/samidorphan): 5 mg/10 mg, 10 mg/10 mg, 15 mg/10 mg and 20 mg/10 mg. (3)

MSN lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 56 and on that basis denies these allegations.

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

ANSWER:

Paragraph 57 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that the Orange Book lists the '466, '111, '960, and '474 patents in connection with NDA No. 213378. MSN lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of Paragraph 57 and on that basis denies these allegations.

MSN LABORATORIES PRIVATE LIMITED'S ANDA PRODUCT

58. By letter dated July 30, 2025, and received by Alkermes no earlier than on August 1, 2025 (the "Notice Letter"), MSN notified Alkermes that MSN had submitted ANDA No. 220726 to the FDA for a generic version of LYBALVI®.

ANSWER:

MSN admits that MSN Laboratories Private Limited provided a notice letter, dated July 30, 2025, to Plaintiffs at their addresses of record. MSN denies the remaining allegations of Paragraph 58.

59. The Notice Letter states that MSN seeks approval from the FDA to engage in the commercial manufacture, use, and sale of MSN's ANDA Product before the expiration of the '466, '111, and '960 Patents. Upon information and belief, MSN intends to – directly or indirectly engage in the commercial manufacture, use, and sale of MSN's ANDA Product promptly upon receiving final FDA approval to do so.

ANSWER:

Paragraph 59 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that MSN Laboratories Private Limited's letter, dated July 30, 2025, states that MSN Laboratories Private Limited submitted ANDA No. 220726 to FDA and

that the ANDA contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certifications") 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, before the expiration of the '466, '111, and '960 patents. MSN denies the remaining allegations of Paragraph 59.

60. By submitting ANDA No. 220726, MSN has represented to the FDA that MSN's ANDA Product has the same active ingredient, dosage form, and strengths as LYBALVI® and is bioequivalent to LYBALVI®.

ANSWER:

Paragraph 60 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that ANDA No. 220726 submitted by MSN Laboratories Private Limited contains the required bioequivalence information. MSN denies the remaining allegations of Paragraph 60.

61. In the Notice Letter, MSN stated that ANDA No. 220726 included a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '960, '111, and '466 Patents. MSN also contended that the '960, '111, and '466 Patents will not be infringed by the commercial manufacture, use, or sale of MSN's ANDA Product.

ANSWER:

MSN admits that MSN Laboratories Private Limited's notice letter, dated July 30, 2025, informed Plaintiffs that ANDA No. 220726 contained certifications pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) ("Paragraph IV Certifications") for the '960, '111, and '466 patents. MSN Laboratories Private Limited's notice letter, dated July 30, 2025, speaks for itself. MSN denies the remaining allegations of Paragraph 61.

62. Upon information and belief, MSN had knowledge of the '960, '111, and '466 Patents when it submitted ANDA No. 220726 to the FDA.

ANSWER:

Paragraph 62 contains legal conclusions to which no response is required. To the extent a

response is required, MSN admits that MSN Laboratories Private Limited's notice letter, dated July 30, 2025, informed Plaintiffs that ANDA No. 220726 contained Paragraph IV Certifications for the '960, '111, and '466 patents. MSN denies the remaining allegations of paragraph 62.

63. Upon information and belief, MSN 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 63 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that the face of the '474 patent states that it issued on August 19, 2025. MSN denies the remaining allegations of Paragraph 63.

64. Upon information and belief, MSN intends to engage in the manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product immediately and imminently upon final FDA approval of ANDA No. 220726.

ANSWER:

Paragraph 64 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that MSN Laboratories Private Limited submitted ANDA No. 220726 to the FDA seeking approval to market MSN's ANDA Product. MSN denies the remaining allegations of Paragraph 64.

65. On or about August 28, 2025, pursuant to an Offer of Confidential Access set forth in the Notice Letter and an agreement between the Parties on August 28, 2025, MSN produced extremely limited portions of its ANDA No. 220726 to Alkermes. MSN refused to produce the entirety of ANDA No. 220726 to Alkermes and refused to provide samples of its ANDA Product or components.

ANSWER:

Paragraph 65 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that, on or about August 28, 2026, MSN Laboratories Private Limited produced relevant portions of MSN's ANDA to Plaintiffs in compliance with the requirements for an Offer of Confidential Access under 21 U.S.C. § 355(j)(5)(C)(i)(III). MSN

denies the remaining allegations of Paragraph 65.

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

ANSWER:

Paragraph 66 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that MSN Laboratories Private Limited's notice letter provided to Alkermes is dated July 30, 2025, and Plaintiffs' Complaint was filed September 5, 2025. MSN denies the remaining allegations of Paragraph 66.

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

67. Plaintiffs incorporate each of the preceding paragraphs 1-66 as if fully set forth herein.

ANSWER:

MSN repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

68. Defendants' submission of ANDA No. 220726, 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 MSN'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:

Denied.

69. 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. 220726 to the FDA.

ANSWER:

Paragraph 69 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that MSN Laboratories Private Limited submitted ANDA No. 220726 to the FDA seeking approval to market MSN's ANDA Product in the United States.

MSN denies the remaining allegations of Paragraph 69.

70. After final FDA approval of ANDA No. 220726, 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 MSN'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. 220726 shall be no earlier than the expiration of the '466 Patent and any additional periods of exclusivity.

ANSWER:

Denied.

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

ANSWER:

Denied.

72. 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:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

Paragraph 74 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that MSN Laboratories Private Limited provided a notice letter, dated July 30, 2025, to Plaintiffs. MSN Laboratories Private Limited's notice letter speaks

for itself. MSN denies the remaining 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:

Denied.

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

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

ANSWER:

MSN repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

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

ANSWER:

Paragraph 77 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that this count purports to arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. MSN denies the remaining allegations of Paragraph 77.

78. Upon information and belief, upon final FDA approval of ANDA No. 220726, 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 MSN's ANDA Product, unless enjoined by the Court.

ANSWER:

Denied.

79. 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. 220726 is approved by marketing MSN's ANDA Product and encouraging doctors and patients to infringe the '466 Patent, unless enjoined by the Court.

ANSWER:

Denied.

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

ANSWER:

Paragraph 80 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that MSN Laboratories Private Limited provided a notice letter, dated July 30, 2025, to Plaintiffs. MSN Laboratories Private Limited's notice letter speaks for itself. MSN denies the remaining allegations of Paragraph 80.

81. 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. 220726 is approved, unless enjoined by the Court, because Defendants know or should know that MSN's ANDA Product is especially made or adapted for use that infringes the '466 Patent, and MSN's ANDA Product is not suitable for substantial noninfringing use.

ANSWER:

Denied.

82. Defendants' infringement is imminent following final FDA approval of ANDA No. 220726.

ANSWER:

Denied.

83. Defendants have notified Alkermes of the submission of ANDA No. 220726 seeking approval to engage in the manufacture, use, sale, or importation of MSN's ANDA Product before the expiration of the '466 Patent.

ANSWER:

MSN admits that MSN Laboratories Private Limited provided a notice letter, dated July 30, 2025, to Plaintiffs at its address of record. MSN Laboratories Private Limited's notice letter speaks for itself. MSN denies the remaining allegations of Paragraph 83.

84. Upon information and belief, Defendants' infringing activity, including the manufacture, use, import, offer to sell, and/or sale of MSN's ANDA Product in the United

States, will begin immediately after final FDA approval.

ANSWER:

Denied.

85. 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 85 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that a justiciable controversy exists under 35 U.S.C. § 271(e)(2) regarding whether MSN's ANDA Product infringes any valid and enforceable claim of the '466 Patent. MSN denies the remaining allegations of Paragraph 85.

86. 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:

Denied.

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

87. Plaintiffs incorporate each of the preceding paragraphs 1-86 as if fully set forth herein.

ANSWER:

MSN repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

88. Defendants' submission of ANDA No. 220726, 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 MSN'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:

Denied.

89. 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. 220726 to the FDA.

ANSWER:

Paragraph 89 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that MSN Laboratories Private Limited submitted ANDA No. 220726 to the FDA seeking approval to market MSN's ANDA Product in the United States. MSN denies the remaining allegations of Paragraph 89.

90. After final FDA approval of ANDA No. 220726, 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 MSN'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. 220726 shall be no earlier than the expiration of the '111 Patent and any additional periods of exclusivity.

ANSWER:

Denied.

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

ANSWER:

Denied.

92. 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:

Denied.

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

ANSWER:

Denied.

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

ANSWER:

Paragraph 94 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that MSN Laboratories Private Limited provided a notice letter, dated July 30, 2025, to Plaintiffs. MSN Laboratories Private Limited's notice letter speaks for itself. MSN denies the remaining 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:

Denied.

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

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

ANSWER:

MSN repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

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

ANSWER:

Paragraph 97 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that this count purports to arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201- 2202. MSN denies the remaining allegations of Paragraph 97.

98. Upon information and belief, upon final FDA approval of ANDA No. 220726, 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 MSN's ANDA Product, unless enjoined by the Court.

ANSWER:

Denied.

99. 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. 220726 is approved by marketing MSN's ANDA Product and encouraging doctors and patients to infringe the '111 Patent, unless enjoined by the Court.

ANSWER:

Denied.

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

ANSWER:

Paragraph 100 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that MSN Laboratories Private Limited provided a notice letter, dated July 30, 2025, to Plaintiffs. MSN Laboratories Private Limited's notice letter speaks for itself. MSN denies the remaining allegations of Paragraph 100.

101. 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. 220726 is approved, unless enjoined by the Court, because Defendants know or should know that MSN's ANDA Product is especially made or adapted for use that infringes the '111 Patent, and MSN's ANDA Product is not suitable for substantial noninfringing use.

ANSWER:

Denied.

102. Defendants' infringement is imminent following final FDA approval of ANDA No. 220726.

ANSWER:

Denied.

103. Defendants have notified Alkermes of the submission of ANDA No. 220726 seeking approval to engage in the manufacture, use, sale, or importation of MSN's ANDA Product before the expiration of the '111 Patent.

ANSWER:

MSN admits that MSN Laboratories Private Limited provided a notice letter, dated July 30, 2025, to Plaintiffs at its address of record. MSN's notice letter speaks for itself. MSN denies the remaining allegations of Paragraph 103.

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

ANSWER:

Denied.

105. 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:

Paragraph 105 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that a justiciable controversy exists under 35 U.S.C. § 271(e)(2) regarding whether MSN's ANDA Product infringes any valid and enforceable claim of the '111 Patent. MSN denies the remaining allegations of Paragraph 105.

106. 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:

Denied.

COUNT V: ALLEGED INFRINGEMENT OF U.S. PATENT NO. 8,778,960 UNDER 35 U.S.C. § 271 BY DEFENDANTS

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

ANSWER:

MSN repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

108. Defendants' submission of ANDA No. 220726 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 MSN's ANDA Product before the expiration of the '960 Patent constituted an act of infringement of one or more claims of the '960 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER:

Denied.

109. 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. 220726 to the FDA.

ANSWER:

Paragraph 109 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that MSN Laboratories Private Limited submitted ANDA No. 220726 to the FDA seeking approval to market MSN's ANDA Product in the United States. MSN denies the remaining allegations of Paragraph 109.

110. After final FDA approval of ANDA No. 220726, Defendants will infringe one or more claims of the '960 Patent, either literally or under the doctrine of equivalents 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. 220726 shall be no earlier than the expiration of the '960 Patent and any additional periods of exclusivity.

ANSWER:

Denied.

111. Defendants have knowledge and are aware of the '960 patent, as evidenced by Defendants' Notice Letter.

ANSWER:

Paragraph 111 contains legal conclusions to which no response is required. To the extent

a response is required, MSN admits that MSN Laboratories Private Limited provided a notice letter to Plaintiffs dated July 30, 2025. MSN Laboratories Private Limited's notice letter speaks for itself. MSN denies the remaining allegations of Paragraph 111.

112. Upon information and belief, MSN's ANDA Product contains olanzapine and samidorphan.

ANSWER:

Admitted.

113. Upon information and belief, MSN's ANDA No. 220726 includes a proposed package insert with directions that instructs healthcare providers, patients, and/or other third parties to administer and/or to prescribe MSN's ANDA Product.

ANSWER:

MSN admits that MSN Laboratories Private Limited's ANDA No. 220726 contains proposed prescribing information. MSN denies the remaining allegations of Paragraph 113.

114. Upon information and belief, upon FDA approval of ANDA No. 220726, MSN intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing of MSN's ANDA Product, unless enjoined by the Court, and MSN's ANDA Product will be administered by patients, healthcare providers, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

ANSWER:

Denied.

115. Upon information and belief, the proposed package insert for MSN's ANDA Product will include a method of reducing antipsychotic induced weight gain comprising administering to a patient in need thereof an effective amount of samidorphan, wherein the antipsychotic is olanzapine.

ANSWER:

Denied.

116. Upon information and belief, the use of MSN's ANDA Product by patients, healthcare providers, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, healthcare providers, and/or other third parties of one or more claims of the '960 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER:

Denied.

117. Upon information and belief, Defendants are aware of, have knowledge of, or are willfully blind to the fact that healthcare providers, patients, and/or other third parties will directly infringe the '960 Patent when they administer MSN's ANDA Product to patients in need of antipsychotic medication to reduce antipsychotic induced weight gain.

ANSWER:

Denied.

118. Upon information and belief, Defendants are aware of, have knowledge of, or are willfully blind to the fact that the proposed package insert for MSN's ANDA Product, if approved, would instruct, encourage, recommend, and/or promote healthcare providers, patients, and/or other third parties to directly infringe the '960 Patent.

ANSWER:

Denied.

119. Upon information and belief, Defendants are aware of, have knowledge of, or are willfully blind to the fact that they will induce and/or contribute to direct infringement of at least one of the claims of the '960 Patent, either literally or under the doctrine of equivalents.

ANSWER:

Denied.

120. Upon information and belief, Defendants are aware of, have knowledge of, or are willfully blind to the fact that MSN's ANDA Product is especially adapted for a use that infringes the '960 Patent, and there is no substantial non-infringing use.

ANSWER:

Denied.

121. Unless Defendants are enjoined from directly or indirectly infringing the '960 Patent, Alkermes will suffer substantial and irreparable harm for which Alkermes has no adequate remedy at law.

ANSWER:

Denied.

COUNT VI: DECLARATORY JUDGMENT OF ALLEGED INFRINGEMENT OF U.S. PATENT NO. 8,778,960 BY THE DEFENDANTS

122. Plaintiffs incorporate each of the preceding paragraphs 1-121 as if fully set forth herein.

ANSWER:

MSN repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

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

ANSWER:

Paragraph 123 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that this count purports to arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201- 2202. MSN denies the remaining allegations of Paragraph 123.

124. Upon information and belief, upon final FDA approval of ANDA No. 220726, Defendants intend to, and will, induce and/or contribute to infringement of one or more claims of the '960 Patent, under 35 U.S.C. § 271(b) and/or (c) either literally or under the doctrine of equivalents by the manufacture, use, sale, or importation of MSN's ANDA Product, unless enjoined by the Court.

ANSWER:

Denied.

125. Defendants have knowledge and are aware of the '960 Patent, as evidenced by Defendants' Notice Letter.

ANSWER:

Paragraph 125 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that MSN Laboratories Private Limited provided a notice letter, dated July 30, 2025, to Plaintiffs. MSN Laboratories Private Limited's notice letter speaks

for itself. MSN denies the remaining allegations of Paragraph 125.

126. Upon information and belief, MSN's ANDA Product contains olanzapine and samidorphan.

ANSWER:

Admitted.

127. Upon information and belief, MSN's ANDA No. 220726 includes a proposed package insert with directions that instructs healthcare providers, patients, and/or other third parties to administer and/or to prescribe MSN's ANDA Product.

ANSWER:

MSN admits that MSN Laboratories Private Limited's ANDA No. 220726 contains proposed prescribing information. MSN denies the remaining allegations of Paragraph 127.

128. Upon information and belief, upon final FDA approval of ANDA No. 220726, MSN intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing of MSN's ANDA Product, unless enjoined by the Court, and MSN's ANDA Product will be administered by patients, healthcare providers, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

ANSWER:

Denied.

129. Upon information and belief, the proposed package insert for MSN's ANDA Product will include a method of reducing antipsychotic induced weight gain comprising administering to a patient in need thereof an effective amount of samidorphan, wherein the antipsychotic is olanzapine.

ANSWER:

Denied.

130. Upon information and belief, the use of MSN's ANDA Product by patients, healthcare providers, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, healthcare providers, and/or other third parties of one or more claims of the '960 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER:

Denied.

131. Upon information and belief, Defendants intend to, and will, actively induce infringement of one or more claims of the '960 Patent, under 35 U.S.C. § 271(b) if/when ANDA No. 220726 is approved by marketing MSN's ANDA Product and encouraging doctors and patients to infringe the '960 Patent, unless enjoined by the Court.

ANSWER:

Denied.

132. Upon information and belief, Defendants will contribute to infringement of one or more claims of the '960 Patent under 35 U.S.C. § 271(c) if/when ANDA No. 220726 is approved, unless enjoined by the Court, because Defendants know or should know that MSN's ANDA Product is especially made or adapted for use in infringing the '960 Patent, and MSN's ANDA Product is not suitable for substantial noninfringing use.

ANSWER:

Denied.

133. Defendants' infringement is imminent following final FDA approval of ANDA No. 220726.

ANSWER:

Denied.

134. Defendants have notified Alkermes of the submission of ANDA No. 220726 seeking approval to engage in the manufacture, use, sale, or importation of MSN's ANDA Product before the expiration of the '960 Patent.

ANSWER:

MSN admits that MSN Laboratories Private Limited provided a notice letter, dated July 30, 2025, to Plaintiffs at its address of record. MSN Laboratories Private Limited's notice letter speaks for itself. MSN denies the remaining allegations of Paragraph 134.

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

ANSWER:

Denied.

136. Thus, a real, substantial, and continuing justiciable controversy exists between the parties hereto as to the infringement of the '960 Patent for which this Court may grant

declaratory relief consistent with Article III of the United States Constitution.

ANSWER:

Paragraph 136 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that a justiciable controversy exists under 35 U.S.C. § 271(e)(2) regarding whether MSN's ANDA Product infringes any valid and enforceable claim of the '960 Patent. MSN denies the remaining allegations of Paragraph 136.

137. Unless Defendants are enjoined from directly or indirectly infringing the '960 Patent, Alkermes will suffer substantial and irreparable harm for which Alkermes has no adequate remedy at law.

ANSWER:

Denied.

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

138. Plaintiffs incorporate each of the preceding paragraphs 1-137 as if fully set forth herein.

ANSWER:

MSN repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

139. Defendants' submission of ANDA No. 220726 to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of MSN'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:

Denied.

140. 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. 220726.

ANSWER:

MSN lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 140 and on that basis denies these allegations.

141. 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. 220726 to the FDA.

ANSWER:

Paragraph 141 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that MSN Laboratories Private Limited submitted ANDA No. 220726 to the FDA seeking approval to market MSN's ANDA Product in the United States. MSN denies the remaining allegations of Paragraph 141

142. After final FDA approval of ANDA No. 220726, 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 MSN'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. 220726 shall be no earlier than the expiration of the '474 Patent and any additional periods of exclusivity.

ANSWER:

Denied.

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

ANSWER:

Denied.

144. 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:

Denied.

145. Defendants know or should know that MSN's ANDA Product is especially adapted for a use that infringes the '474 Patent, and there is no substantial non-infringing use.

ANSWER:

Denied.

146. 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.

ANSWER:

Paragraph 146 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that the Orange Book lists the submission date of the '474 Patent as August 19, 2025. MSN lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and on that basis denies these allegations.

147. Upon information and belief, Defendants have knowledge of the '474 Patent, as evidenced by the public notice of the '474 Patent.

ANSWER:

Paragraph 147 contains legal conclusions to which no response is required. To the extent a response is required, MSN denies the remaining allegations of paragraph 147.

148. 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:

Denied.

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

149. Plaintiffs incorporate each of the preceding paragraphs 1-148 as if fully set forth herein.

ANSWER:

MSN repeats and incorporates by reference its responses in each of the preceding paragraphs as if fully set forth herein.

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

ANSWER:

Paragraph 150 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that this count purports to arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. MSN denies the remaining allegations of Paragraph 150.

151. Upon information and belief, upon final FDA approval of ANDA No. 220726, 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 MSN's ANDA Product, unless enjoined by the Court.

ANSWER:

Denied.

152. 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) if/when ANDA No. 220726 is approved by marketing MSN's ANDA Product and encouraging doctors and patients to infringe the '474 Patent, unless enjoined by the Court.

ANSWER:

Denied.

153. 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.

ANSWER:

Paragraph 153 contains legal conclusions to which no response is required. To the extent a response is required, MSN admits that the Orange Book lists the submission date of the '474 Patent as August 19, 2025. MSN lacks knowledge or information sufficient to form a belief

about the truth of the remaining allegations in this paragraph and on that basis denies these allegations.

154. Upon information and belief, Defendants have knowledge of the '474 Patent, as evidenced by the public notice of the '474 Patent.

ANSWER:

Paragraph 154 contains legal conclusions to which no response is required. To the extent a response is required, MSN denies the remaining allegations of paragraph 154.

155. 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. 220726 is approved, unless enjoined by the Court, because Defendants know or should know that MSN's ANDA Product is especially made or adapted for use in infringing the '474 Patent, and MSN's ANDA Product is not suitable for substantial noninfringing use.

ANSWER:

Denied.

156. Defendants' infringement is imminent following final FDA approval of ANDA No. 220726.

ANSWER:

Denied.

157. Defendants have notified Alkermes of the submission of ANDA No. 220726 seeking approval to engage in the manufacture, use, sale, or importation of MSN's ANDA Product before the expiration of the '474 Patent.

ANSWER:

Denied.

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

ANSWER:

Denied.

159. 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:

Denied.

160. 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:

Denied.

RESPONSE TO PRAYER FOR RELIEF

All remaining allegations not specifically admitted herein are denied. MSN further denies that Plaintiffs are entitled to any of the relief set forth in its "Prayer for Relief" or to any relief whatsoever.

DEFENSES

Without any admission or implication as to burden of proof and expressly reserving its right to assert any additional defenses or counterclaims that discovery may reveal, MSN asserts the following defenses:

FIRST DEFENSE
(NON-INFRINGEMENT OF THE '466, '111, '960, AND '474 PATENTS BY MSN'S ANDA PRODUCT)

The manufacture, use, sale, offer for sale, and/or importation of MSN's ANDA Product have not, do not, and will not infringe, induce infringement of, and/or contribute to the infringement of any valid and/or enforceable claims of the '466, '111, '960, and '474 patents, either literally or by the doctrine of equivalents.

SECOND DEFENSE
(INVALIDITY OF THE '466, '111, '960, AND '474 PATENTS)

One or more claims of the '466, '111, '960, and '474 patents are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including without limitation, one or more of Sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

THIRD DEFENSE
(FAILURE TO STATE A CLAIM)

Plaintiffs have failed to state a claim upon which relief can be granted.

FOURTH DEFENSE
(SAFE HARBOR UNDER 35 U.S.C. § 271(e)(1))

Pursuant to 35 U.S.C. § 271(e)(1), MSN's actions do not constitute infringement.

FIFTH DEFENSE
(ADDITIONAL DEFENSES DISCOVERY MAY REVEAL)

Defendants reserve all defenses available under the Federal Rules of Civil Procedure and the U.S. patent laws and any additional defenses or counterclaims that discovery may reveal including that Plaintiffs have failed to aver any facts supporting that this is an exceptional case and an award of attorneys' fees under 35 U.S.C. § 285.

RESERVATION OF DEFENSES

MSN hereby reserves any and all defenses that are available under the Federal Rules of Civil Procedure, Local Patent Rules, and U.S. Patent Law 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, including unenforceability.

COUNTERCLAIMS OF MSN PHARMACEUTICALS, INC. AND MSN LABORATORIES PRIVATE LIMITED

Defendants/Counterclaim-Plaintiffs MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited bring the following Counterclaims against Plaintiffs/Counterclaim-Defendants Alkermes, Inc. and Alkermes Pharma Ireland Limited (collectively, "Alkermes"), and state as follows:

NATURE OF THE ACTION

1. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C), based on an actual controversy between the parties to declare that MSN Laboratories Private Limited's is free to continue to seek approval of its Abbreviated New Drug Application ("ANDA") No. 220726, and upon approval by the U.S. Food and Drug Administration ("FDA"), to engage in commercial manufacture, importation, sale, and/or offer for sale of the olanzapine and samidorphan tablets described in MSN Laboratories Private Limited's ANDA No. 220726 ("MSN's ANDA Product").

THE PARTIES

2. MSN Laboratories Private Limited is an entity organized and existing under the laws of the Republic of India, with a place of business at MSN House, Plot No. C-24, Industrial Estate, Sanathnagar, Hyderabad, 500018, Telangana, India.

3. MSN Pharmaceuticals Inc. is an entity incorporated and existing under the laws of the State of Delaware having a place of business at 20 Duke Road, Piscataway, NJ 08854.

4. Alkermes, Inc. purports to be an entity organized and existing under the laws of the Commonwealth of Pennsylvania, with a place of business at 900 Winter Street, Waltham, Massachusetts 02451.

5. Alkermes Pharma Ireland Limited purports to be 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.

6. Alkermes Pharma Ireland Limited purports to be the assignee of U.S. Patent Nos. 11,707,466 ("'466 Patent"), 11,951,111 ("'111 Patent"), 8,778,960 ("'960 Patent"), and 12,390,474 ("'474 Patent") (collectively, "Patents-in-Suit").

7. Alkermes, Inc. purports to be the holder of New Drug Application ("NDA") No. 213378 for the marketing and sale of LYBALVI®.

JURISDICTION AND VENUE

8. These Counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and/or 21 U.S.C. § 355(j)(5)(C).

9. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331, 1337(a) and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under 21 U.S.C. § 355(j)(5)(C).

10. This Court has personal jurisdiction over Alkermes, Inc. because it has availed itself of the rights and privileges and subjected itself to the jurisdiction of this forum by suing MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited in this District, and/or because Alkermes conducts substantial business in, and has regular systemic contact with, this District.

11. This Court has personal jurisdiction over Alkermes Pharma Ireland Limited because it has availed itself of the rights and privileges and subjected itself to the jurisdiction of this forum by suing MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited in this District, and/or because Alkermes conducts substantial business in, and has regular systemic contact with, this District.

12. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400.

BACKGROUND

13. On September 5, 2025, Alkermes filed a Complaint for Patent Infringement ("Complaint") in this Court alleging that the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product before the expiration of the Patents-in-Suit would constitute infringement of those patents, either literally or under the doctrine of equivalents. Alkermes further alleged that MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited will actively induce infringement of, and/or contribute to infringement by others of the Patents-in-Suit.

14. By virtue of Alkermes's Complaint, an immediate and justiciable controversy exists between each of MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited, on the one hand, and Alkermes, on the other, regarding whether MSN's ANDA Product infringes any valid and enforceable claims of the Patents-in-Suit.

PATENTS-IN-SUIT

15. The face of the '466 patent indicates it was issued by the U.S. Patent and Trademark Office ("USPTO") on or about July 25, 2023.

16. The face of the '111 patent indicates it was issued by the USPTO on or about April 9, 2024.

17. The face of the ’960 patent indicates it was issued by the USPTO on or about July 15, 2014.

18. The face of the ’474 patent indicates it was issued by the USPTO on or about August 19, 2025.

19. Alkermes purports to have the right to enforce the ’466, ’111, ’960, and ’474 patents.

20. On information and belief, Alkermes caused the FDA to list the ’466, ’111, ’960, and ’474 patents in the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) in connection with NDA No. 213378 for LYBALVI®.

21. By maintaining the listing of the ’466, ’111, ’960, and ’474 patents in the Orange Book for NDA No. 213378 for LYBALVI®, Alkermes has represented that the ’466, ’111, ’960, and ’474 patents cover a combination product of olanzapine/samidorphan, and that a claim of patent infringement may reasonably be asserted against any ANDA applicant, including MSN, that is not licensed by Alkermes and files an ANDA seeking approval to market olanzapine/samidorphan tablets for which LYBALVI® is the reference listed drug before the expiration of the ’466, ’111, ’960, and ’474 patents.

MSN’S ANDA NO. 220726

22. MSN Laboratories Private Limited submitted ANDA No. 220726 to the FDA seeking approval to engage in the commercial marketing of MSN’s ANDA Product before the expiration of the Patents-in-Suit.

23. In accordance with the requirements of 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.52(c), MSN Laboratories Private Limited sent Alkermes a notice letter dated July 30, 2025

("MSN's Notice Letter"), stating that MSN's ANDA included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification(s)"), alleging that the '466, '111, AND '960 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of MSN's ANDA Product.

24. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), MSN's Notice Letter included an Offer of Confidential Access ("OCA") to MSN's ANDA for the holder of NDA No. 213378 and owner of the '466, '111, and '960 patents.

25. MSN Laboratories Private Limited's OCA complied with the requirements of 21 U.S.C. § 355(j)(5)(C)(i)(III), which states in relevant part that the offer shall be for "confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

26. Alkermes did not agree to the original terms of MSN Laboratories Private Limited's OCA. Alkermes agreed to modified terms of MSN's OCA through which MSN produced portions of ANDA No. 220726 to Counterclaim-Defendants' counsel.

27. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) of the Federal Drug and Cosmetic Act, MSN's Notice Letter included a detailed statement of the factual and legal bases for MSN's Paragraph IV Certifications ("MSN's Detailed Statement").

28. Alkermes's receipt of MSN's Notice Letter initiated a 45-day statutory period during which Alkermes had the opportunity to file an action for patent infringement with respect to MSN's ANDA.

29. On September 5, 2025, Alkermes filed this infringement action asserting the '466, '111, '960, and '474 patents against MSN.

FIRST COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '466 PATENT BY MSN'S ANDA PRODUCT)

30. MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited reallege and incorporate by reference each of the preceding paragraphs as if fully set forth herein.

31. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* By virtue of Alkermes's allegations of infringement against MSN, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Alkermes and each of MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited concerning non-infringement of the '466 Patent by MSN's ANDA Product.

32. MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited seek a declaration that no valid or enforceable claim of the '466 Patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of MSN's ANDA Product.

33. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), MSN's Detailed Statement provides factual and legal bases for why MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited have not infringed, are not infringing, and will not infringe any

valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '466 Patent.

34. MSN's Detailed Statement expressly reserved the right to assert additional grounds of non-infringement, invalidity, and unenforceability beyond those provided in MSN's Detailed Statement.

35. Because Alkermes maintains that the commercial manufacture, use, offer for sale, or sale of MSN's ANDA Product would infringe the '466 Patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of MSN's ANDA Product within the United States has not infringed and will not infringe, directly and/or indirectly, the '466 Patent.

36. MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited are entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of MSN's ANDA Product has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the '466 Patent.

SECOND COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '466 PATENT)

37. MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited reallege and incorporate by reference each of the preceding paragraphs as if fully set forth herein.

38. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and seeks a declaration that the claims of the '466 patent are invalid. By virtue of Alkermes's allegations of infringement against MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of

rights by this Court exists between Alkermes and each of MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited concerning the invalidity of the claims of the '466 Patent.

39. Because Alkermes maintains and MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited deny that the '466 patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '466 Patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including Sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

40. MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited are entitled to a declaration that the claims of the '466 Patent are invalid.

THIRD COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '111 PATENT BY MSN'S ANDA PRODUCT)

41. MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited reallege and incorporate by reference each of the preceding paragraphs as if fully set forth herein.

42. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* By virtue of Alkermes's allegations of infringement against MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Alkermes and each of MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited concerning non-infringement of the '111 Patent by MSN's ANDA Product.

43. MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited seek a declaration that no valid or enforceable claim of the '111 Patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of MSN's ANDA Product.

44. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), MSN's Detailed Statement provides factual and legal bases for why MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited have not infringed, are not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '111 Patent.

45. MSN's Detailed Statement expressly reserved the right to assert additional grounds of non-infringement, invalidity, and unenforceability beyond those provided in MSN's Detailed Statement.

46. Because Alkermes maintains that the commercial manufacture, use, offer for sale, or sale of MSN's ANDA Product would infringe the '111 Patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of MSN's ANDA Product within the United States has not infringed and will not infringe, directly and/or indirectly, the '111 Patent.

47. MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited are entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of MSN's ANDA Product has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the '111 patent.

FOURTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '111 PATENT)

48. MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited reallege and incorporate by reference each of the preceding paragraphs as if fully set forth herein.

49. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, and seeks a declaration that the claims of the '111 Patent are invalid. By virtue of Alkermes's allegations of infringement against MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Alkermes and MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited concerning the invalidity of the claims of the '111 Patent.

50. Because Alkermes maintains and MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited deny that the '111 Patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '111 Patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including Sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

51. MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited are entitled to a declaration that the claims of the '111 Patent are invalid.

FIFTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '960 PATENT BY MSN'S ANDA PRODUCT)

52. MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited reallege and incorporate by reference each of the preceding paragraphs as if fully set forth herein.

53. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* By virtue of Alkermes's allegations of infringement against MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Alkermes and each of MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited concerning non-infringement of the '960 Patent by MSN's ANDA Product.

54. MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited seek a declaration that no valid or enforceable claim of the '960 Patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of MSN's ANDA Product.

55. In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II), MSN's Detailed Statement provides factual and legal bases for why MSN has not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '960 Patent.

56. MSN's Detailed Statement expressly reserved the right to assert additional grounds of non-infringement, invalidity, and unenforceability beyond those provided in MSN's Detailed Statement.

57. Because Alkermes maintains that the commercial manufacture, use, offer for sale, or sale of MSN's ANDA Product would infringe the '960 Patent, a declaration of rights between the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of MSN's ANDA Product within the United States has not infringed and will not infringe, directly and/or indirectly, the '960 Patent.

58. MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited are entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of MSN's ANDA Product has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the '960 Patent.

SIXTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '960 PATENT)

59. MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited reallege and incorporate by reference each of the preceding paragraphs as if fully set forth herein.

60. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and seeks a declaration that the claims of the '960 patent are invalid. By virtue of Alkermes's allegations of infringement against MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Alkermes and each of MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited concerning the invalidity of the claims of the '960 patent.

61. Because Alkermes maintains and MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited deny that the '960 Patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the

'960 Patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including Sections 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

62. MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited are entitled to a declaration that the claims of the '960 Patent are invalid.

SEVENTH COUNTERCLAIM
(DECLARATION OF NON-INFRINGEMENT OF THE '474 PATENT BY MSN'S ANDA PRODUCT)

63. MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited reallege and incorporate by reference each of the preceding paragraphs as if fully set forth herein.

64. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* By virtue of Alkermes's allegations of infringement against MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Alkermes and MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited concerning non-infringement of the '474 Patent by MSN's ANDA Product.

65. MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited seek a declaration that no valid or enforceable claim of the '474 Patent has been infringed or will be infringed, directly and/or indirectly, by the manufacture, use, importation, sale, or offer for sale of MSN's ANDA Product.

66. Because Alkermes maintains that the commercial manufacture, use, offer for sale, or sale of MSN's ANDA Product would infringe the '474 Patent, a declaration of rights between

the parties is appropriate and necessary to establish that the commercial manufacture, use, importation, offer for sale, or sale of MSN's ANDA Product within the United States has not infringed and will not infringe, directly and/or indirectly, the '474 Patent.

67. MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited are entitled to a declaration that the manufacture, use, importation, offer for sale and/or sale of MSN's ANDA Product has not infringed and will not infringe, directly and/or indirectly, any valid and enforceable claim of the '474 Patent.

EIGHTH COUNTERCLAIM
(DECLARATION OF INVALIDITY OF THE '474 PATENT)

68. MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited reallege and incorporate by reference each of the preceding paragraphs as if fully set forth herein.

69. This counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*; and seeks a declaration that the claims of the '474 Patent are invalid. By virtue of Alkermes's allegations of infringement against MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited, a case of actual, substantial and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Alkermes and each of MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited concerning the invalidity of the claims of the '474 Patent.

70. Because Alkermes maintains and MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited deny that the '474 Patent and the claims thereof are valid, a declaration of rights between the parties is appropriate and necessary to establish that the '474 Patent and the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including Sections

101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double-patenting and/or any other judicially created requirements for patentability and enforceability of patents.

71. MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited are entitled to a declaration that the claims of the ’474 Patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Defendants/Counterclaim-Plaintiffs MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited respectfully request that this Court enter a Judgment and Order:

A. dismissing the Complaint, and the claims for relief contained therein, with prejudice;

B. declaring that MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited and MSN’s ANDA Products have not infringed, are not infringing, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the ’466, ’111, ’960, and ’474 patents;

C. declaring that the claims of the ’466, ’111, ’960, and ’474 patents are invalid;

D. declaring this an exceptional case under 35 U.S.C. § 285 and awarding MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited attorney fees, costs, and expenses; and

E. granting MSN Pharmaceuticals, Inc. and MSN Laboratories Private Limited such other and further relief as this Court deems just and proper.

Dated: November 10, 2025

Respectfully submitted,

s/ Eric I. Abraham

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Attorneys for Defendant MSN Inc.

CERTIFICATE PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

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

I hereby certify that the matter in controversy in this action is related to the following actions in the District Court for the District of New Jersey:

- *Alkermes, Inc. et al v. Apotex Corp. et al*, 1:25-14977 (KMW-AMD)
- *Alkermes, Inc. et al v. Teva Pharmaceuticals, Inc. et al*, 1:25-14685 (KMW-AMD)

Dated: November 10, 2025

Respectfully submitted,

By: *s/ Eric I. Abraham*
Draft

CERTIFICATE OF SERVICE

I hereby certify that on November 10, 2025, I caused a true and correct copy of the foregoing document to be served via electronic mail on counsel of record in this matter.

Dated: November 10, 2025

Respectfully submitted,

By: *s/ Eric I. Abraham*
Draft