Andrew J. Miller
WINDELS MARX LANE &
MITTENDORF, LLP
One Giralda Farms
Madison, NJ 07940
(973) 966-3200
Attorneys for Defendants
Slayback Pharma LLC and
Slayback Pharma India LLP

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

ALKERMES PHARMA IRELAND LIMITED, Plaintiff, v. SLAYBACK PHARMA LLC and SLAYBACK PHARMA INDIA LLP, Defendants.	C.A. No. 3:23-3794

DEFENDANTS SLAYBACK PHARMA LLC AND SLAYBACK PHARMA INDIA LLP'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO COMPLAINT

Defendants Slayback Pharma LLC ("Slayback") and Slayback Pharma India LLP ("Slayback India") (collectively, "Defendants") respond to the Complaint of Plaintiff Alkermes Pharma Ireland Limited ("Alkermes" or "Plaintiff") as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the Patent Laws of the United States, 35 U.S.C. §100, et seq., arising from Slayback's filing of New Drug Application ("NDA") No. 218395 ("Slayback's NDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market an infringing version of ANJESO® (meloxicam injection, 30 mg/mL) at a dose of 30 mg (the "Proposed Drug Product") prior to the expiration of United States Patent Nos. 10,463,673 (the "'673 patent"), 10,471,067 (the "'067 patent"),

10,709,713 (the "'713 patent"), 10,881,663 (the "'663 patent"), and 11,458,145 (the "'145 patent") (collectively, the "Patents-in-Suit"), all owned by Plaintiff.

ANSWER:

Paragraph 1 contains legal conclusions to which no response is required. To the extent a response is required, Defendants admit Plaintiff purports to bring an action for infringement of United States Patent Nos. 10,463,673 ("the '673 patent"), 10,471,067 ("the '067 patent"), 10,709,713 ("the '713 patent"), 10,881,663 ("the '663 patent"), and 11,458,145 ("the '145 patent") under the patent laws of the United States, but deny that Plaintiff is entitled to such relief. Slayback admits that Slayback submitted a New Drug Application ("NDA") No. 218395 ("Slayback's NDA") to the U.S. Food and Drug Administration ("FDA") seeking approval for the matters described in Slayback's NDA and the product that is described in Slayback's NDA ("Slayback's Proposed NDA Product"). Defendants deny the remaining allegations of paragraph 1 of the Complaint.

THE PARTIES

2. Plaintiff 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:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 2 of the Complaint and, on that basis, denies them.

3. On information and belief, Slayback is an entity organized and existing under the laws of the State of Delaware, having a principal place of business at 301 Carnegie Center, Suite 303, Princeton, New Jersey 08540.

ANSWER:

Admitted.

4. On information and belief, Slayback India is a limited liability partnership organized under the laws of India, having a principal place of business at 310, 3rd Floor, Manjeera Trinity Corporate, JNTU – Hitech City Road, KPHB Phase 3, Kukutpally Hyderabad, Telangana, 500072, India.

ANSWER:

Admitted.

JURISDICTION AND VENUE

5. This is an action for patent infringement arising under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. This Court has jurisdiction over the subject matter of this action under 35 U.S.C. § 271, 28 U.S.C. §§ 1331, 1338, 2201, and/or 2202.

ANSWER:

Paragraph 5 contains legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest that this Court has subject matter jurisdiction over this action. Defendants deny the remaining allegations of paragraph 5 of the Complaint.

6. On information and belief, Slayback has its principal place of business in New Jersey at 301 Carnegie Center, Suite 303, Princeton, New Jersey 08540.

ANSWER:

Admitted.

7. On information and belief, Slayback, either directly or through one or more of its subsidiaries or agents, manufactures, markets, imports, distributes, and/or sells pharmaceutical drug products, including drug products, throughout the United States, including in this Judicial District.

ANSWER:

Paragraph 7 contains legal conclusions to which no response is required. To the extent a response is required, for the purposes of this action only, Slayback does not contest personal jurisdiction. Slayback denies the remaining allegations of paragraph 7 of the Complaint.

8. Slayback is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5005359.

ANSWER:

Admitted.

9. Slayback is registered with the State of New Jersey's Division of Revenue & Enterprise Services as a business in the State of New Jersey under Entity ID No. 0400399320.

ANSWER:

Admitted.

10. Slayback's website states it is "a New Jersey-based company focused on complex generic and specialty pharmaceutical products." Slayback Pharma LLC, https://slaybackpharma.com/about-us/ (last visited July 14, 2023).

ANSWER:

Admitted.

11. Slayback sent Plaintiff a letter dated June 1, 2023 ("Slayback's Notice Letter") stating that Slayback filed Slayback's NDA with the FDA seeking approval to engage in the commercial manufacture, use, or sale within the United States, including, on information and belief, in this Judicial District, of the Proposed Drug Product prior to the expiration of the Patents-in-Suit.

ANSWER:

Slayback admits it filed Slayback's NDA seeking approval of the matters described therein. Slayback's Notice Letter is a document that speaks for itself. Slayback denies the remaining allegations of paragraph 11 of the Complaint.

12. This Court thus has personal jurisdiction over Slayback because, *inter alia*, it has purposely availed itself of the privilege of acting within New Jersey by committing an act of patent infringement under 35 U.S.C. § 271(e)(2).

ANSWER:

Paragraph 12 contains legal conclusions to which no response is required. To the extent a response is required, for the purposes of this action only, Slayback does not contest personal jurisdiction. Slayback denies the remaining allegations of paragraph 12 of the Complaint.

13. This Court has personal jurisdiction over Slayback because, *inter alia*, Slayback: (1) has a principal place of business in New Jersey; and (2) has purposefully availed itself of the privilege of doing business in New Jersey by registering with the State of New Jersey's Division of Revenue & Enterprise Services as a business operating in New Jersey under Entity ID No. 0400399320 and registering with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5005359.

ANSWER:

Paragraph 13 contains legal conclusions to which no response is required. To the extent a response is required, for the purposes of this action only, Slayback does not contest personal jurisdiction. Slayback denies the remaining allegations of paragraph 13 of the Complaint.

14. This Court also has personal jurisdiction over Slayback because, *inter alia*, Slayback: (1) maintains extensive and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey; (2) imports generic versions of branded pharmaceutical products for sale and use throughout the United States, including in New Jersey; and (3) on information and belief, derives substantial revenue from the sale of its products in this Judicial District.

ANSWER:

Paragraph 14 contains legal conclusions to which no response is required. To the extent a response is required, for the purposes of this action only, Slayback does not contest personal jurisdiction. Slayback denies the remaining allegations of paragraph 14 of the Complaint.

15. On information and belief, this court has jurisdiction over Slayback India. On information and belief, Slayback India is in the business of, *inter alia*, developing, manufacturing, marketing, importing, distributing, and/or selling pharmaceutical drug products, including generic drug products.

ANSWER:

Paragraph 15 contains legal conclusions to which no response is required. To the extent a response is required, for purposes of this action only, Slayback India does not contest personal

jurisdiction in this judicial district. Slayback India denies the remaining allegations of paragraph 15 of the Complaint.

16. On information and belief, Slayback India directly or indirectly develops, manufactures, markets, distributes, and/or sells pharmaceutical drug products, including generic drug products, throughout the United States, including in this Judicial District.

ANSWER:

Denied.

17. On information and belief, Slayback India purposefully has conducted and continues to conduct business in this Judicial District in concert with Slayback.

ANSWER:

Paragraph 17 contains legal conclusions to which no response is required. To the extent a response is required, for purposes of this action only, Slayback India does not contest personal jurisdiction in this judicial district. Slayback and Slayback India deny the remaining allegations of paragraph 17 of the Complaint.

18. On information and belief, this Judicial District is a likely destination for Slayback's Proposed Drug Product.

ANSWER:

Paragraph 18 contains legal conclusions to which no response is required. To the extent a response is required, for purposes of this action only, Slayback does not contest personal jurisdiction in this judicial district. Slayback denies the remaining allegations of paragraph 18 of the Complaint.

19. On information and belief, Slayback and Slayback India intend a future course of conduct that includes acts of patent infringement in this Judicial District.

ANSWER:

Paragraph 19 contains legal conclusions to which no response is required. To the extent a response is required, for purposes of this action only, Slayback and Slayback India do not contest

venue in this judicial district. Slayback and Slayback India deny the remaining allegations of paragraph 19 of the Complaint.

20. On information and belief, Slayback and Slayback India operate as interrelated corporate entities.

ANSWER:

Paragraph 20 contains legal conclusions to which no response is required. To the extent a response is required, for purposes of this action only, Slayback and Slayback India do not contest personal jurisdiction in this judicial district. Slayback and Slayback India deny the remaining allegations of paragraph 20 of the Complaint.

21. On information and belief, Slayback is the parent corporation of Slayback India.

ANSWER:

Admitted.

22. On information and belief, Slayback and Slayback India each act as an agent of the other and work together to, *inter alia*, develop, manufacture, obtain regulatory approval, market, sell, and distribute generic copies of branded pharmaceutical products throughout the United States, including in this Judicial District.

ANSWER:

Paragraph 22 contains legal conclusions to which no response is required. To the extent a response is required, for purposes of this action only, Slayback and Slayback India do not contest venue in this judicial district. Slayback and Slayback India deny the remaining allegations of paragraph 22 of the Complaint.

23. In addition to the foregoing, this Court has personal jurisdiction over Slayback India because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Plaintiff's claims arise under federal law; (b) Slayback India is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) on information and belief, Slayback India has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting NDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Slayback India satisfies due process.

ANSWER:

Paragraph 23 contains legal conclusions to which no response is required. To the extent a response is required, for purposes of this action only, Slayback India does not contest personal jurisdiction in this judicial district. Slayback India denies the remaining allegations of paragraph 23 of the Complaint.

24. This Court has personal jurisdiction over Defendants also because they have taken advantage of the jurisdiction of this Court by filing claims and/or counterclaims in this Court. On information and belief, Defendants have previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in numerous prior patent cases. For example, Defendants have previously been sued in this Judicial District and have availed themselves of New Jersey courts through the assertion of counterclaims in suits brought in New Jersey, and have not challenged personal jurisdiction. *See, e.g., Valeant Pharms. North America, LLC et al v. Zydus Pharms. USA, Inc. et al*, Civil Action No. 18-13635 (BRM)(LDW); *Kythera Biopharmaceuticals, Inc. v. Slayback Pharma LLC*, Civil Action No. 18-16012 (BRM)(TJB). Defendants have also consented to personal jurisdiction in additional suits brought in New Jersey. *See, e.g., Bausch & Lomb , Inc. et al v. Slayback Pharma LLC et al*, Civil Action No. 21- 16766 (RK)(RLS).

ANSWER:

Paragraph 24 contains legal conclusions to which no response is required. To the extent a response is required, for purposes of this action only, Defendants do not contest personal jurisdiction in this judicial district. Defendants deny the remaining allegations of paragraph 24 of the Complaint.

25. Venue is proper in this district for Slayback pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Slayback 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 25 contains legal conclusions to which no response is required. To the extent a response is required, for purposes of this action only, Slayback does not contest venue in this judicial district. Slayback denies the remaining allegations of paragraph 25 of the Complaint.

26. Venue is proper in this Court as to Slayback for the reasons set forth above and for other reasons that will be presented to the Court if such venue is challenged.

ANSWER:

Paragraph 26 contains legal conclusions to which no response is required. To the extent a response is required, for purposes of this action only, Slayback does not contest venue in this judicial district. Slayback denies the remaining allegations of paragraph 26 of the Complaint.

27. Venue is proper in this district as to Slayback India pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Slayback India is a limited liability partnership existing under the laws of India and may be sued in any judicial district.

ANSWER:

Paragraph 27 contains legal conclusions to which no response is required. To the extent a response is required, for purposes of this action only, Slayback India does not contest venue in this judicial district. Slayback India denies the remaining allegations of paragraph 27 of the Complaint.

BACKGROUND
The Patents-in-Suit and ANJESO® Drug Product

28. NDA No. 210583 (the "RLD NDA") was for ANJESO® intravenous meloxicam injection, 30 mg/mL. ANJESO® is the Reference Listed Drug for Slayback's NDA.

ANSWER:

Defendants admit, on information and belief, that NDA No. 210583 was approved for intravenous meloxicam injection, 30 mg/mL under the trade mark ANJESO®. Slayback admits that Slayback's NDA is directed to intravenous meloxicam injection, 30 mg/mL. Defendants deny any remaining allegations of paragraph 28 of the Complaint.

29. The RLD NDA was approved on February 20, 2020. Intravenous meloxicam injection, 30 mg/mL, has been sold in the United States under the trademark ANJESO® pursuant to the RLD NDA.

ANSWER:

Defendants admit, on information and belief, that the intravenous meloxicam injection, 30 mg/mL "has been sold" in the United States under the trademark ANJESO®. On information and belief, Defendants deny the remaining allegations of paragraph 29, including any implication that ANJESO® product is currently sold in the United States.

30. The Patents-in-Suit were each listed in the FDA's publication titled Approved Drug Products with Therapeutic Equivalence Valuations (the "Orange Book").

ANSWER:

Defendants admit, on information and belief, that the Patents-in-Suit were listed in the Orange Book in connection with ANJESO®. Defendants deny the remaining allegations of paragraph 30 of the Complaint.

31. ANJESO® was indicated for management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics.

ANSWER:

Defendants admit, on information and belief, that Plaintiff's intravenous meloxicam injection, 30 mg/mL "was" indicated for a medical purpose as stated in the approved label for ANJESO®. On information and belief, Defendants deny the remaining allegations of paragraph 31, including any implication that ANJESO® product is currently sold in the United States.

A. The '673 Patent

32. Plaintiff owns U.S. Patent No. 10,463,673. On November 5, 2019, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '673 patent, entitled "Nanoparticulate meloxicam formulations." A copy of the '673 patent is attached as Exhibit A. The '673 patent is listed in the Orange Book as covering ANJESO® (RLD NDA).

ANSWER:

Defendants admit that the cover page of the '673 patent indicates it issued on November

5, 2019, but specifically deny it was duly and lawfully issued. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding ownership of the '673 patent, on that basis, deny them. Defendants admit that what purports to be a copy of the '673 patent is attached to the Complaint as Exhibit A. The '673 patent is a document that speaks for itself. Defendants admit that the '673 patent was listed in the Orange Book for NDA No. 210583, but said NDA is "discontinued." Defendants deny the remaining allegations of paragraph 32 of the Complaint.

B. The '067 Patent

33. Plaintiff owns U.S. Patent No. 10,471,067. On November 12, 2019, the USPTO duly and lawfully issued the '067 patent, entitled "Nanoparticulate meloxicam formulations." A copy of the '067 patent is attached as Exhibit B. The '067 patent is listed in the Orange Book as covering ANJESO® (RLD NDA).

ANSWER:

Defendants admit that the cover page of the '067 patent indicates it issued on November 12, 2019, but specifically deny it was duly and lawfully issued. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding ownership of the '067 patent, on that basis, deny them. Defendants admit that what purports to be a copy of the '067 patent is attached to the Complaint as Exhibit B. The '067 patent is a document that speaks for itself. Defendants admit that the '067 patent was listed in the Orange Book for NDA No. 210583, but said NDA is "discontinued." Defendants deny the remaining allegations of paragraph 33 of the Complaint.

C. The '713 Patent.

34. Plaintiff owns U.S. Patent No. 10,709,713. On July 14, 2020, the USPTO duly and lawfully issued the '713 patent, entitled "Nanoparticulate meloxicam formulations." A copy of the '713 patent is attached as Exhibit C. The '713 patent is listed in the Orange Book as covering ANJESO® (RLD NDA).

ANSWER:

Defendants admit that the cover page of the '713 patent indicates it issued on July 14, 2020, but specifically deny it was duly and lawfully issued. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding ownership of the '713 patent, on that basis, deny them. Defendants admit that what purports to be a copy of the '713 patent is attached to the Complaint as Exhibit C. The '713 patent is a document that speaks for itself. Defendants admit that the '713 patent was listed in the Orange Book for NDA No. 210583, but said NDA is "discontinued." Defendants deny the remaining allegations of paragraph 34 of the Complaint.

D. The '663 Patent

35. Plaintiff owns U.S. Patent No. 10,881,663. On January 5, 2021, the USPTO duly and lawfully issued the '663 patent, entitled "Method of treating pain in elderly patients with mild renal impairment." A copy of the '663 patent is attached as Exhibit D. The '663 patent is listed in the Orange Book as covering ANJESO® (RLD NDA). E. The '145 Patent

ANSWER:

Defendants admit that the cover page of the '663 patent indicates it issued on January 5, 2021, but specifically deny it was duly and lawfully issued. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding ownership of the '663 patent, on that basis, deny them. Defendants admit that what purports to be a copy of the '663 patent is attached to the Complaint as Exhibit D. The '663 patent is a document that speaks for itself. Defendants admit that the '663 patent was listed in the Orange Book for NDA No. 210583, but said NDA is "discontinued." Defendants deny the remaining allegations of paragraph 35 of the Complaint.

E. The '145 Patent

36. Plaintiff owns U.S. Patent No. 11,458,145. On October 4, 2022, the USPTO duly and lawfully issued the '145 patent, entitled "Methods of administering intravenous meloxicam in a bolus dose." A copy of the '145 patent is attached as Exhibit E. The '145 patent is listed in the Orange Book as covering ANJESO® (RLD NDA).

ANSWER:

Defendants admit that the cover page of the '145 patent indicates it issued on October 4, 2022, but specifically deny it was duly and lawfully issued. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding ownership of the '145 patent, on that basis, deny them. Defendants admit that what purports to be a copy of the '145 patent is attached to the Complaint as Exhibit E. The '145 patent is a document that speaks for itself. Defendants admit that the '145 patent was listed in the Orange Book for NDA No. 210583, but said NDA is "discontinued." Defendants deny the remaining allegations of paragraph 36 of the Complaint.

Slayback's Infringing NDA Submission

37. On information and belief, as set forth in Slayback's Notice Letter, Slayback filed Slayback's NDA with the FDA seeking approval to engage in the commercial manufacture, use, or sale of its Proposed Drug Product prior to the expiration of the Patents-in-Suit.

ANSWER:

Slayback admits it filed Slayback's NDA seeking approval of the matters described therein. Slayback denies the remaining allegations of paragraph 37 of the Complaint.

38. Slayback's NDA includes a certification with respect to each of the Patents-in- Suit under § 505(b)(2)(A)(iv) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) ("Paragraph IV Certification").

ANSWER:

Slayback admits that Slayback's Notice Letter notified Plaintiff of its Slayback's NDA certification that the claims of each of the Patents-in- Suit are invalid, unenforceable, and/or will not be infringed by Slayback's Proposed NDA Product. Slayback's Notice Letter is a document

that speaks for itself. Slayback denies the remaining allegations of paragraph 38 of the Complaint.

39. On or about June 1, 2023, Slayback's Notice Letter was sent to Plaintiff, in which Slayback represented that it had filed Slayback's NDA with the FDA seeking approval to engage in the commercial manufacture, use, or sale of its Proposed Drug Product prior to the expiration of the Patents-in-Suit that are listed in the Orange Book for ANJESO®.

ANSWER:

Slayback admits it filed Slayback's NDA seeking approval of the matters described therein. Slayback's Notice Letter is a document that speaks for itself. Slayback denies the remaining allegations of paragraph 39 of the Complaint.

40. Under statute, Slayback has committed an act of infringement by filing Slayback's NDA with a Paragraph IV Certification.

ANSWER:

Denied.

41. In Slayback's Notice Letter, Slayback included a "Detailed Statement of the Factual and Legal Basis for Slayback Pharma LLC's Assertion of Invalidity, Unenforceability, or Non-Infringement" of the Patents-in-Suit, which sets forth the basis for its Paragraph IV Certification.

ANSWER:

Slayback's Notice Letter is a document that speaks for itself. Slayback denies the remaining allegations of paragraph 41 of the Complaint.

42. In Slayback's Notice Letter, Slayback states that the established name for its Proposed Drug Product is "meloxicam injection, 30 mg/mL."

ANSWER:

Slayback's Notice Letter is a document that speaks for itself. Slayback denies the remaining allegations of paragraph 42 of the Complaint.

43. In its Detailed Statement, Slayback did not set forth any grounds for invalidity or unenforceability of the Patents-in-Suit.

ANSWER:

Slayback's Notice Letter is a document that speaks for itself. Slayback denies the remaining allegations of paragraph 43 of the Complaint.

44. Slayback's Notice Letter contained an "Offer of Confidential Access." The terms to the Offer of Confidential Access were unreasonable, and Plaintiff attempted to negotiate access on more reasonable terms.

ANSWER:

Slayback's Notice Letter is a document that speaks for itself. Slayback denies the remaining allegations of paragraph 44 of the Complaint.

45. Only after a protracted negotiation regarding its Offer of Confidential Access, Slayback belatedly produced a multi-thousand page volume of confidential documents 41 days after the date on Slayback's Notice Letter.

ANSWER:

Slayback admits that it produced thousands of pages of confidential information to Plaintiff before Plaintiff filed this Complaint. Slayback denies the remaining allegations of paragraph 45 of the Complaint.

46. On information and belief, fact and expert discovery will show that the Proposed Drug Product infringes one or more claims of the Patents-in-Suit.

ANSWER:

Denied.

ACTS GIVING RISE TO THIS SUIT

47. Pursuant to Section 505 of the Federal Food, Drug and Cosmetic Act ("FFDCA"), Slayback filed Slayback's NDA with the FDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product before the Patents-in-Suit expire.

ANSWER:

Slayback admits it filed Slayback's NDA seeking approval of the matters described therein. Slayback denies the remaining allegations of paragraph 47 of the Complaint.

48. On information and belief, following FDA approval of Slayback's NDA, Defendants will make, use, sell, or offer to sell Slayback's Proposed Drug Product throughout the United States, or import such products into the United States.

ANSWER:

Slayback admits it filed Slayback's NDA seeking approval of the matters described therein. Slayback denies the remaining allegations of paragraph 48 of the Complaint.

49. In connection with the filing of Slayback's NDA as described above, Slayback provided a written certification to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(b)(2)(A)(iv), alleging that the claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the activities described in Slayback's Paragraph IV Certification.

ANSWER:

Admitted.

50. On or about June 1, 2023, Slayback sent written notice of Slayback's Paragraph IV Certification to Plaintiff (*i.e.*, Slayback's Notice Letter) regarding the Patents-in-Suit. Slayback's Notice Letter alleged that the claims of the Patents-in-Suit will not be infringed by the activities described in Slayback's NDA. Slayback's Notice Letter also informed Plaintiff that Slayback seeks approval to market Slayback's Proposed Drug Product before the Patents-in-Suit expire. Slayback specifically directed Slayback's Notice Letter to Plaintiff.

ANSWER:

Slayback admits that by letter dated June 1, 2023, Slayback notified Plaintiff of its NDA certification that the claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by Slayback's Proposed NDA Product. Slayback's Notice Letter is a document that speaks for itself. Slayback denies the remaining allegations of paragraph 50 of the Complaint.

51. Based on a reasonable review of Slayback's Paragraph IV Certification, Slayback's confidential information, and publicly available information, Plaintiff is informed and believes filing of Slayback's NDA infringes and the Proposed Drug Product will infringe valid patent claims of the Patents-in-Suit, and has therefore brought this action.

ANSWER:

Denied.

52. This action is being commenced within the expiration of 45 days from the date Plaintiff received Slayback's Notice Letter.

ANSWER:

Paragraph 52 contains legal conclusions to which no response is required.

COUNT I
Infringement of the '673 Patent.

53. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER:

Defendants incorporate by reference their responses to paragraphs 1-52 as if fully set forth herein.

54. Slayback, by the submission of its Paragraph IV Certification as part of Slayback's NDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product, prior to the expiration of the '673 patent.

ANSWER:

Slayback admits it filed Slayback's NDA seeking approval of the matters described therein. Slayback denies the remaining allegations of paragraph 54 of the Complaint.

55. Slayback's NDA has been pending before the FDA since at least June 1, 2023, the date appearing on Slayback's Notice Letter to Plaintiff.

ANSWER:

Admitted.

56. On information and belief, the Proposed Drug Product is covered by at least one or more properly construed claims of the '673 patent, either literally or under the doctrine of equivalents.

ANSWER:

Denied.

57. Slayback's submission of Slayback's NDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product, prior to the expiration of the '673 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Denied.

58. There is a justiciable controversy between the parties hereto as to the infringement of the '673 patent.

ANSWER:

Denied.

59. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will infringe one or more claims of the '673 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States.

ANSWER:

Denied.

60. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Slayback will induce infringement of one or more claims of the '673 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States. On information and belief, upon FDA approval of Slayback's NDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '673 patent and knowledge that their acts are encouraging infringement.

ANSWER:

Denied.

61. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will contributorily infringe one or more claims of the '673 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States. On information and belief, Defendants have had and continue to have knowledge that Slayback's Proposed Drug Product is especially adapted for a use that infringes one or more claims of the '673 patent and that there is no substantial non-infringing use for Slayback's Proposed Drug Product.

ANSWER:

Denied.

62. Plaintiff will be substantially and irreparably damaged and harmed if Defendants' infringement of the '673 patent is not enjoined.

ANSWER:

Denied.

63. Plaintiff does not have an adequate remedy at law.

ANSWER:

Denied.

64. Slayback did not contest the validity of any of the claims of the '673 patent in Slayback's Notice Letter. If Slayback had a factual or legal basis to contest the validity of the claims of the '673 patent, it was required by applicable regulations to state such a basis in Slayback's Notice Letter. See 21 CFR § 314.52(c).

ANSWER:

Slayback's Notice Letter is a document that speaks for itself. Slayback denies the remaining allegations of paragraph 64 of the Complaint.

65. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Denied.

COUNT II
Infringement of the '067 Patent

66. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER:

Defendants incorporate by reference their responses to paragraphs 1-65 as if fully set forth herein.

67. Slayback, by the submission of its Paragraph IV Certification as part of Slayback's NDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture,

use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product, prior to the expiration of the '067 patent.

ANSWER:

Slayback admits it filed Slayback's NDA seeking approval of the matters described therein. Slayback denies the remaining allegations of paragraph 67 of the Complaint.

68. Slayback's NDA has been pending before the FDA since at least June 1, 2023, the date appearing on Slayback's Notice Letter to Plaintiff.

ANSWER:

Admitted.

69. On information and belief, the Proposed Drug Product is covered by at least one or more properly construed claims of the '067 patent, either literally or under the doctrine of equivalents.

ANSWER:

Denied.

70. Slayback's submission of Slayback's NDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product, prior to the expiration of the '067 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Denied.

71. There is a justiciable controversy between the parties hereto as to the infringement of the '067 patent.

ANSWER:

Denied.

72. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will infringe one or more claims of the '067 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States.

ANSWER:

Denied.

73. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will induce infringement of one or more claims of the '067 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States. On information and belief, upon FDA approval of Slayback's NDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '067 patent and knowledge that their acts are encouraging infringement.

ANSWER:

Denied.

74. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will contributorily infringe one or more claims of the '067 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States. On information and belief, Defendants have had and continue to have knowledge that Slayback's Proposed Drug Product is especially adapted for a use that infringes one or more claims of the '067 patent and that there is no substantial non-infringing use for Slayback's Proposed Drug Product.

ANSWER:

Denied.

75. Plaintiff will be substantially and irreparably damaged and harmed if Defendants' infringement of the '067 patent is not enjoined.

ANSWER:

Denied.

76. Plaintiff does not have an adequate remedy at law.

ANSWER:

Denied.

77. Slayback did not contest the validity of any of the claims of the '067 patent in Slayback's Notice Letter. If Slayback had a factual or legal basis to contest the validity of the claims of the '067 patent, it was required by applicable regulations to state such a basis in Slayback's Notice Letter. See 21 CFR § 314.52(c).

ANSWER:

Slayback's Notice Letter is a document that speaks for itself. Slayback denies the

remaining allegations of paragraph 77 of the Complaint.

78. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Denied.

COUNT III
Infringement of the '713 Patent

79. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER:

Defendants incorporate by reference their responses to paragraphs 1-78 as if fully set forth herein.

80. Slayback, by the submission of its Paragraph IV Certification as part of Slayback's NDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product, prior to the expiration of the '713 patent.

ANSWER:

Slayback admits it filed Slayback's NDA seeking approval of the matters described therein. Slayback denies the remaining allegations of paragraph 80 of the Complaint.

81. Slayback's NDA has been pending before the FDA since at least June 1, 2023, the date appearing on Slayback's Notice Letter to Plaintiff.

ANSWER:

Admitted.

82. On information and belief, the Proposed Drug Product is covered by at least one or more properly construed claims of the '713 patent, either literally or under the doctrine of equivalents.

ANSWER:

Denied.

83. Slayback's submission of Slayback's NDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product, prior to the expiration of the '713 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Denied.

84. There is a justiciable controversy between the parties hereto as to the infringement of the '713 patent.

ANSWER:

Denied.

85. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will infringe one or more claims of the '713 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States.

ANSWER:

Denied.

86. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will induce infringement of one or more claims of the '713 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States. On information and belief, upon FDA approval of Slayback's NDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '713 patent and knowledge that their acts are encouraging infringement.

ANSWER:

Denied.

87. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will contributorily infringe one or more claims of the '713 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States. On information and belief, Defendants have had and continue to have knowledge that Slayback's Proposed Drug Product is especially adapted for a use that infringes one or more claims of the '713 patent and that there is no substantial non-infringing use for Slayback's Proposed Drug Product.

ANSWER:

Denied.

88. Plaintiff will be substantially and irreparably damaged and harmed if Defendants' infringement of the '713 patent is not enjoined.

ANSWER:

Denied.

89. Plaintiff does not have an adequate remedy at law.

ANSWER:

Denied.

90. Slayback did not contest the validity of any of the claims of the '713 patent in Slayback's Notice Letter. If Slayback had a factual or legal basis to contest the validity of the claims of the '713 patent, it was required by applicable regulations to state such a basis in Slayback's Notice Letter. See 21 CFR § 314.52(c).

ANSWER:

Slayback's Notice Letter is a document that speaks for itself. Slayback denies the remaining allegations of paragraph 90 of the Complaint.

91. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Denied.

COUNT IV
Infringement of the '663 Patent

92. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER:

Defendants incorporate by reference their responses to paragraphs 1-91 as if fully set forth herein.

93. Slayback, by the submission of its Paragraph IV Certification as part of Slayback's NDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product, prior to the expiration of the '663 patent.

ANSWER:

Slayback admits it filed Slayback's NDA seeking approval of the matters described therein. Slayback denies the remaining allegations of paragraph 93 of the Complaint.

94. Slayback's NDA has been pending before the FDA since at least June 1, 2023, the date appearing on Slayback's Notice Letter to Plaintiff.

ANSWER:

Admitted.

95. On information and belief, the Proposed Drug Product is covered by at least one or more properly construed claims of the '663 patent, either literally or under the doctrine of equivalents.

ANSWER:

Denied.

96. Slayback's submission of Slayback's NDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product, prior to the expiration of the '663 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Denied.

97. There is a justiciable controversy between the parties hereto as to the infringement of the '663 patent.

ANSWER:

Denied.

98. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will infringe one or more claims of the '663 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States.

ANSWER:

Denied.

99. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will induce infringement of one or more claims of the '663 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States. On information and belief, upon FDA approval of Slayback's NDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '663 patent and knowledge that their acts are encouraging infringement.

ANSWER:

Denied.

100. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will contributorily infringe one or more claims of the '663 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States. On information and belief, Defendants have had and continue to have knowledge that Slayback's Proposed Drug Product is especially adapted for a use that infringes one or more claims of the '663 patent and that there is no substantial non-infringing use for Slayback's Proposed Drug Product.

ANSWER:

Denied.

101. Plaintiff will be substantially and irreparably damaged and harmed if Defendants' infringement of the '663 patent is not enjoined.

ANSWER:

Denied.

102. Plaintiff does not have an adequate remedy at law.

ANSWER:

Denied.

103. Slayback did not contest the validity of any of the claims of the '663 patent in Slayback's Notice Letter. If Slayback had a factual or legal basis to contest the validity of the claims of the '663 patent, it was required by applicable regulations to state such a basis in Slayback's Notice Letter. See 21 CFR § 314.52(c).

ANSWER:

Slayback's Notice Letter is a document that speaks for itself. Slayback denies the remaining allegations of paragraph 103 of the Complaint.

104. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Denied.

COUNT V
Infringement of the '145 Patent

105. Plaintiff repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER:

Defendants incorporate by reference their responses to paragraphs 1-104 as if fully set forth herein.

106. Slayback, by the submission of its Paragraph IV Certification as part of Slayback's NDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product, prior to the expiration of the '145 patent.

ANSWER:

Slayback admits it filed Slayback's NDA seeking approval of the matters described therein. Slayback denies the remaining allegations of paragraph 106 of the Complaint.

107. Slayback's NDA has been pending before the FDA since at least June 1, 2023, the date appearing on Slayback's Notice Letter to Plaintiff.

ANSWER:

Admitted.

108. On information and belief, the Proposed Drug Product is covered by at least one or more properly construed claims of the '145 patent, either literally or under the doctrine of equivalents.

ANSWER:

Denied.

109. Slayback's submission of Slayback's NDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed Drug Product, prior to the expiration of the '145 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Denied.

110. There is a justiciable controversy between the parties hereto as to the infringement of the '145 patent.

ANSWER:

Denied.

111. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will infringe one or more claims of the '145 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States.

ANSWER:

Denied.

112. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will induce infringement of one or more claims of the '145 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States. On information and belief, upon FDA approval of Slayback's NDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '145 patent and knowledge that their acts are encouraging infringement.

ANSWER:

Denied.

113. Unless enjoined by this Court, upon FDA approval of Slayback's NDA, Defendants will contributorily infringe one or more claims of the '145 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Slayback's Proposed Drug Product in the United States. On information and belief, Defendants have had and continue to have knowledge that Slayback's Proposed Drug Product is especially adapted for a use that infringes one or more claims of the '145 patent and that there is no substantial non-infringing use for Slayback's Proposed Drug Product.

ANSWER:

Denied.

114. Plaintiff will be substantially and irreparably damaged and harmed if Defendants' infringement of the '145 patent is not enjoined.

ANSWER:

Denied.

115. Plaintiff does not have an adequate remedy at law.

ANSWER:

Denied.

116. Slayback did not contest the validity of any of the claims of the '145 patent in Slayback's Notice Letter. If Slayback had a factual or legal basis to contest the validity of the claims of the '145 patent, it was required by applicable regulations to state such a basis in Slayback's Notice Letter. See 21 CFR § 314.52(c).

ANSWER:

Slayback's Notice Letter is a document that speaks for itself. Slayback denies the remaining allegations of paragraph 116 of the Complaint.

117. This case is an exceptional one, and Plaintiff is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Denied.

SEPARATE DEFENSES

Without prejudice to the admissions and denials set forth in its Answer, and without admitting any allegations of the Complaint not expressly admitted, Slayback asserts the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest with Plaintiff.

First Separate Defense
(Non-infringement of the '673 Patent)

The manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed NDA Product has not infringed, and would not, if marketed, infringe, contribute to the infringement of, or induce the infringement of, any valid and/or enforceable claim of the '673 Patent.

Second Separate Defense
(Invalidity of the '673 Patent)

The claims of the '673 Patent are invalid for failure to comply with one or more of the conditions for patentability under the patent laws of the United States, including, but not limited to, one or more of pre- or post AIA 35 U.S.C. §§ 101, 102, 103 and/or 112, double patenting or any judicially created bases for invalidation or unenforceability.

Third Separate Defense
(Non-infringement of the '067 Patent)

The manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed NDA Product has not infringed, and would not, if marketed, infringe, contribute to the infringement of, or induce the infringement of, any valid and/or enforceable claim of the '067 Patent.

Fourth Separate Defense
(Invalidity of the '067 Patent)

The claims of the '067 Patent are invalid for failure to comply with one or more of the conditions for patentability under the patent laws of the United States, including, but not limited to, one or more of pre- or post AIA 35 U.S.C. §§ 101, 102, 103 and/or 112, double patenting or any judicially created bases for invalidation or unenforceability.

Fifth Separate Defense
(Non-infringement of the '713 Patent)

The manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed NDA Product has not infringed, and would not, if marketed, infringe, contribute to the infringement of, or induce the infringement of, any valid and/or enforceable claim of the '713 Patent.

Sixth Separate Defense
(Invalidity of the '713 Patent)

The claims of the '713 Patent are invalid for failure to comply with one or more of the conditions for patentability under the patent laws of the United States, including, but not limited to, one or more of pre- or post AIA 35 U.S.C. §§ 101, 102, 103 and/or 112, double patenting or any judicially created bases for invalidation or unenforceability.

Seventh Separate Defense
(Non-infringement of the '663 Patent)

The manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed NDA Product has not infringed, and would not, if marketed, infringe, contribute to the infringement of, or induce the infringement of, any valid and/or enforceable claim of the '663 Patent.

Eighth Separate Defense
(Invalidity of the '663 Patent)

The claims of the '663 Patent are invalid for failure to comply with one or more of the conditions for patentability under the patent laws of the United States, including, but not limited to, one or more of pre- or post AIA 35 U.S.C. §§ 101, 102, 103 and/or 112, double patenting or any judicially created bases for invalidation or unenforceability.

Ninth Separate Defense
(Non-infringement of the '145 Patent)

The manufacture, use, sale, offer for sale, or importation into the United States of Slayback's Proposed NDA Product has not infringed, and would not, if marketed, infringe, contribute to the infringement of, or induce the infringement of, any valid and/or enforceable claim of the '145 Patent.

Tenth Separate Defense
(Invalidity of the '145 Patent)

The claims of the '145 Patent are invalid for failure to comply with one or more of the conditions for patentability under the patent laws of the United States, including, but not limited to, one or more of pre- or post AIA 35 U.S.C. §§ 101, 102, 103 and/or 112, double patenting or any judicially created bases for invalidation or unenforceability.

Eleventh Separate Defense
(Failure to State a Claim)

Plaintiff's Complaint fails to state a claim upon which relief can be granted and fails to state a claim for exceptional case. Plaintiff has failed to show that Slayback's Proposed NDA Product described by Slayback's NDA and Slayback's Notice Letter infringes any claim of any of the Patents-in-Suit, as Slayback's Proposed NDA Product does meet the claim elements of any claim of the Patents-in-Suit for at least the reasons stated in Slayback's Notice Letter.

Twelfth Separate Defense
(No Injury or Damage)

Plaintiff may not seek injunctive relief against Defendants because Plaintiff's alleged damages are not immediate or irreparably, and Plaintiff therefore has an adequate remedy at law.

Reservation of Defenses

Defendants reserve the right to assert additional defenses pending further investigation and discovery.

RESPONSE TO PLAINTIFF'S PRAYER FOR RELIEF

The remainder of Plaintiff's complaint recites a prayer for relief for which no response is required. To the extent a response is required, Defendants deny that Plaintiff is entitled to any judgment or relief against Defendants and, therefore, specifically denies paragraphs (A) through (L) of Plaintiff's Prayer for Relief.

COUNTERCLAIMS

Defendants and Counterclaim-Plaintiffs Slayback Pharma LLC and Slayback Pharma India LLP (collectively, "Slayback") by way of counterclaim against Plaintiff and Counterclaim-Defendant Alkermes Pharma Ireland Limited ("Alkermes") state as follows:

THE PARTIES

1. Slayback Pharma LLC is an entity organized and existing under the laws of the State of Delaware, having a principal place of business at 301 Carnegie Center, Suite 303, Princeton, New Jersey 08540.

2. Slayback Pharma India LLP is a limited liability partnership organized under the laws of India, having a principal place of business at 310, 3rd Floor, Manjeera Trinity Corporate, JNTU – Hitech City Road, KPHB Phase 3, Kukutpally Hyderabad, Telangana, 500072, India.

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

JURISDICTION AND VENUE

4. This is an action for declaratory judgment pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, together with such further and other relief that may be necessary or proper. The basis for declaratory judgment is an actual controversy between

Slayback and Counterclaim Defendant arising under the under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq*. This Court has subject matter jurisdiction over the action based on 28 U.S.C. §§ 2201, 2202, 1331, 1338(a), and 1367 and 21 U.S.C. §355(c)(3)(D).

5. This Court has personal jurisdiction over Alkermes because, among other reasons, Alkermes subjected itself to the jurisdiction of this Court by filing its Complaint here.

6. Venue is proper in this District with respect to Alkermes as to these Counterclaims under 28 U.S.C. §§ 1391(b)-(c) and 1400(b) at least because the assertion of Alkermes's infringement action against Slayback in this District gave rise to these Counterclaims. Alkermes asserts in its Complaint that venue is proper in this District.

7. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(c) because, on information and belief, Alkermes is a foreign company.

SLAYBACK'S PROPOSED NDA PRODUCT

8. Slayback is a pharmaceutical company focused on development and sales of complex generic and specialty pharmaceutical products.

9. Slayback invested in the development of a new drug product directed to pain management in patients suffering from renal impairment utilizing the active pharmaceutical ingredient meloxicam.

10. Slayback filed New Drug Application ("NDA") No. 218395 ("Slayback's NDA") to obtain FDA approval and engage in the commercial manufacture, use, sale, offer for sale, or importation of meloxicam injection, 30 mg/mL ("Slayback's Proposed NDA Product").

11. By letter dated June 1, 2023, Slayback sent Alkermes a Notice Letter ("Slayback's Notice Letter"), pursuant to 21 U.S.C. § 355(b)(3) and 21 C.F.R. § 314.52, notifying Alkermes and Baudax Bio, Inc. that Slayback's NDA includes Paragraph IV Certifications with respect to

U.S. Patent Nos. 9,974,746; 10,463,673; 10,471,067; 10,709,713; 10,881,663; 11,253,478; and 11,458,145 (collectively "Orange Book Patents").

12. Slayback's Notice Letter contained a Detailed Statement setting forth the factual and legal basis for why Slayback's Proposed NDA Product does not infringe, has not infringed, and would not, if marketed, sold, or used, infringe any valid and enforceable claims of the Orange Book Patents, either directly or indirectly, and either literally or under the doctrine of equivalents.

THE ORANGE BOOK PATENTS AND DISCONTINUED NDA NO. 210583

13. U.S. Patent No. 9,974,746 ("the '746 Patent"), entitled "Reduction of Flake-Like Aggregation in Nanoparticulate Active Agent Compositions," issued on May 22, 2018. On information and belief, the '746 Patent is now owned by Alkermes.

14. U.S. Patent No. 10,463,673 ("the '673 Patent") entitled "Nanoparticulate Meloxicam Formulations" issued on Nov. 59974746, 2019. On information and belief, the '673 Patent is now owned by Alkermes.

15. U.S. Patent No. 10,471,067 ("the '067 Patent") entitled "Nanoparticulate Meloxicam Formulations" issued on Nov. 12, 2019. On information and belief, the '067 Patent is now owned by Alkermes.

16. U.S. Patent No. 10,709,713 ("the '713 Patent") entitled "Nanoparticulate Meloxicam Formulations," issued on Jul. 14, 2020. On information and belief, the '713 Patent is now owned by Alkermes.

17. U.S. Patent No. 10,881,663 ("the '663 Patent") entitled "Method of Treating Pain in Elderly Patients with Mild Renal Impairment," issued on Jan. 5, 2021. On information and belief, the '663 Patent is now owned by Alkermes.

18. U.S. Patent No. 11,253,478 ("the '478 Patent") entitled "Reduction of Flake-Like Aggregation in Nanoparticulate Active Agent Compositions," issued on February 22, 2022. On

information and belief, the '478 Patent is now owned by Alkermes.

19. U.S. Patent No. 11,458,145 ("the '145 Patent") entitled "Method of Administering Intravenous Meloxicam in a Bolus Dose," issued on Oct. 4, 2022. On information and belief, the '145 Patent is now owned by Alkermes.

20. The Orange Book Patents are all listed in the Electronic Orange Book for NDA No. 210583.

21. On information and belief, intravenous meloxicam injection, 30 mg/mL was previously sold in the United States under the trademark ANJESO® pursuant to NDA No. 210583.

22. On information and belief, the current Marketing Status at the FDA for NDA No. 210583 is "Discontinued."

23. On information and belief, there is no commercial product currently sold in the United States pursuant to NDA No. 210583.

24. On information and belief, Baudax Bio Inc. (a non-party) is the holder of NDA No. 210583 intravenous meloxicam injection, 30 mg/mL.

THE ACTUAL CONTROVERSY

25. Alkermes filed the Complaint in this Court against Slayback alleging that the filing of Slayback's NDA No. 218395 infringed certain Orange Book Patents and that any commercial manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product would infringe said patents.

26. An actual and justiciable controversy exists regarding the Orange Book Patents by virtue of the filing of the Complaint by Alkermes. Thus, an actual controversy exists between Slayback and Alkermes as to whether any valid claim of the Orange Book Patents are or will be

infringed by the commercial manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product.

27. Slayback requires an immediate declaration of its rights vis-à-vis Alkermes with respect to Slayback's Proposed NDA Product and the Orange Book Patents.

COUNTERCLAIM I
(Declaratory Judgment of Non-Infringement of the '673 Patent)

28. Slayback repeats and realleges the allegations contained in Paragraphs 1 - 27 of its Counterclaims as if fully set forth herein.

29. This counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

30. In its Complaint, Plaintiff asserts that Slayback has infringed the '673 Patent by Slayback's submission of NDA No. 218395 to the FDA seeking to obtain approval for the manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product.

31. This counterclaim is for a declaration that Slayback has not infringed, induced infringement or contributed to the infringement, does not infringe, induce infringement or contribute to infringement through submission of Slayback's NDA, and will not infringe, induce infringement or contribute to infringement, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product of any valid and enforceable claim of the '673 Patent.

32. Plaintiff maintains, and Slayback denies, that Slayback's Proposed NDA Product will infringe the '673 Patent.

33. No claim of the '673 Patent is infringed or will be infringed by the manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product for at least the

reasons set forth in the Detailed Statement of Slayback's Notice Letter, dated June 1, 2023, which has previously been served on Plaintiff.

34. Actual and justiciable controversies exist between Plaintiff and Slayback regarding the infringement of the '673 Patent.

35. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, Slayback requests a declaration from the Court that the manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product does not infringe the claims of the '673 Patent.

COUNTERCLAIM II
(Declaratory Judgment of Invalidity of the '673 Patent)

36. Slayback repeats and realleges the allegations contained in Paragraphs 1 - 35 of its Counterclaims as if fully set forth herein.

37. This counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

38. This counterclaim is for a declaration that each and every claim of the '673 Patent is invalid for obviousness because it fails to satisfy the requirements of 35 U.S.C. § 103.

39. The claims of the '673 Patent are directed, *inter alia*, to an injectable pharmaceutical dosage form consisting of: 30 mg of meloxicam, or a salt thereof, wherein the meloxicam is in the form of particles having an effective average particle size of less than about 200 nm, polyvinylpyrrolidone, sodium deoxycholate, sucrose, and water.

40. Injectable formulations of meloxicam were known in the prior art and it was further known that they possessed potential advantages over oral formulations.

41. Prior art articles Combe, *et al.*, *Inflamm Res*, 2001, *50 (Supplement 1)*, S10-S16 ("Combe") and Narjes, *et al.*, *Br J Clin Pharmacol*, 1996, *41*, 135-139 ("Narjes") disclose

intramuscular injections of meloxicam and mention that the injectable formulations demonstrated more beneficial pharmacokinetic properties than an oral dosage form because of faster onset of action. Narjes reported the use of 30 mg meloxicam injection.

42. Prior art Mobic Package Insert, Boehringer Ingelheim Pharmaceuticals, Inc., 2000 discloses meloxicam has poor aqueous solubility.

43. Prior art U.S. Patent Application No. 2003/0031719 ("the '719 publication") discloses drugs with low solubility in water can have significant benefits when formulated as a suspension of sub-micron particles and the particles must be small enough in diameter to safely pass through the capillaries of the patient.

44. Prior art United States Patent No. 5,145,684 ("the '684 patent") discloses that the rate of dissolution of a particulate drug can increase with increasing surface area, *i.e.*, decreasing particle size, and the particles should not flocculate or agglomerate. The '684 patent, along with United States Patent No. 5,302,401 ("the '401 patent") and United States Patent No. 5,085,864 ("the '864 patent") further teach the utility of surface modifiers and other stabilizing excipients such as polyvinylpyrrolidone, sodium deoxycholate, and sucrose in nanoparticulate formulations. The '684 patent states that the particle sizes of such nanoparticulate suspension are in the range of 3 nm - 400 nm.

45. The claims of the '673 Patent are thus invalid under 35 U.S.C. § 103 because the alleged invention claimed therein is obvious to a person of ordinary skill in the art ("POSA") in view of the prior art, including, but not limited to the art mentioned above.

46. Slayback reserves the right to provide additional bases for invalidity or unenforceability of the '673 Patent in its contentions, responses to discovery requests, expert

reports and/or pleadings filed and/or served as this action progresses.

47. Actual and justiciable controversies exist between Plaintiff and Slayback regarding the validity and enforceability of the ’673 Patent.

48. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, Slayback requests a declaration from the Court that each claim of the ’673 Patent is invalid.

COUNTERCLAIM III
(Declaratory Judgment of Non-Infringement of the ’067 Patent)

49. Slayback repeats and realleges the allegations contained in Paragraphs 1 - 48 of its Counterclaims as if fully set forth herein.

50. This counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

51. In its Complaint, Plaintiff asserts that Slayback has infringed the ’067 Patent by Slayback’s submission of NDA No. 218395 to the FDA seeking to obtain approval for the manufacture, use, sale, offer for sale, or importation of Slayback’s Proposed NDA Product.

52. This counterclaim is for a declaration that Slayback has not infringed, induced infringement or contributed to the infringement, does not infringe, induce infringement or contribute to infringement through submission of Slayback’s NDA, and will not infringe, induce infringement or contribute to infringement, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, or importation of Slayback’s Proposed NDA Product of any valid and enforceable claim of the ’067 Patent.

53. Plaintiff maintains, and Slayback denies, that Slayback’s Proposed NDA Product will infringe the ’067 Patent.

54. No claim of the ’067 Patent is infringed or will be infringed by the manufacture,

use, sale, offer for sale, or importation of Slayback's Proposed NDA Product for at least the reasons set forth in the Detailed Statement of Slayback's Notice Letter, dated June 1, 2023, which has previously been served on Plaintiff.

55. Actual and justiciable controversies exist between Plaintiff and Slayback regarding the infringement of the '067 Patent.

56. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq*., Slayback requests a declaration from the Court that the manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product does not infringe the claims of the '067 Patent.

COUNTERCLAIM IV
(Declaratory Judgment of Invalidity of the '067 Patent)

57. Slayback repeats and realleges the allegations contained in Paragraphs 1 - 56 of its Counterclaims as if fully set forth herein.

58. This counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

59. This counterclaim is for a declaration that each and every claim of the '067 Patent is invalid for obviousness because it fails to satisfy the requirements of 35 U.S.C. § 103.

60. The claims of the '067 Patent are directed to, *inter alia*, to an injectable pharmaceutical dosage form comprising 30 mg of meloxicam, or a salt thereof, wherein the meloxicam is in the form of particles having effective average particle size of less than or about 2000 nm, polyvinylpyrrolidone, sodium deoxycholate, sucrose, and water, wherein the dosage form does not comprise a combination of meloxicam and a vasomodulator.

61. Injectable formulations of meloxicam were known in the prior art, and it was further known that they possessed potential advantages over oral formulations.

62. Prior art articles Combe and Narjes disclose intramuscular injections of meloxicam and mention that the injectable formulations demonstrated more beneficial pharmacokinetic properties than an oral dosage form because of faster onset of action. Narjes reported the use of 30 mg meloxicam injection.

63. Prior art Mobic Package Insert, Boehringer Ingelheim Pharmaceuticals, Inc., 2000 discloses meloxicam has poor aqueous solubility.

64. The '719 publication discloses drugs with low solubility in water can have significant benefits when formulated as a suspension of sub-micron particles and the particles must be small enough in diameter to safely pass through the capillaries of the patient.

65. The '684 patent discloses that the rate of dissolution of a particulate drug can increase with increasing surface area, *i.e.*, decreasing particle size, and the particles should not flocculate or agglomerate. The '684 patent, along with the '401 patent and the '864 patent further teach the utility of surface modifiers and other stabilizing excipients such as polyvinylpyrrolidone, sodium deoxycholate, and sucrose in such injectable nanoparticulate formulations. The '684 patent states that the particle sizes of such nanoparticulate suspension are in the range of 3 nm - 400 nm.

66. The claims of the '067 Patent are thus invalid under 35 U.S.C. § 103 because the alleged invention claimed therein is obvious to a POSA in view of the prior art, including, but not limited to the art mentioned above.

67. Slayback reserves the right to provide additional bases for invalidity or unenforceability of the '067 Patent in its contentions, responses to discovery requests, expert reports and/or pleadings filed and/or served as this action progresses.

68. Actual and justiciable controversies exist between Plaintiff and Slayback regarding

the validity and enforceability of the ’067 Patent.

69. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq*., Slayback requests a declaration from the Court that each claim of the ’067 Patent is invalid.

COUNTERCLAIM V
(Declaratory Judgment of Non-Infringement of the ’713 Patent)

70. Slayback repeats and realleges the allegations contained in Paragraphs 1 - 69 of its Counterclaims as if fully set forth herein.

71. This counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

72. In its Complaint, Plaintiff asserts that Slayback has infringed the ’713 Patent by Slayback’s submission of NDA No. 218395 to the FDA seeking to obtain approval for the manufacture, use, sale, offer for sale, or importation of Slayback’s Proposed NDA Product.

73. This counterclaim is for a declaration that Slayback has not infringed, induced infringement or contributed to the infringement, does not infringe, induce infringement or contribute to infringement through submission of Slayback’s NDA, and will not infringe, induce infringement or contribute to infringement, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, or importation of Slayback’s Proposed NDA Product of any valid and enforceable claim of the ’713 Patent.

74. Plaintiff maintains, and Slayback denies, that Slayback’s Proposed NDA Product will infringe the ’713 Patent.

75. No claim of the ’713 Patent is infringed or will be infringed by the manufacture, use, sale, offer for sale, or importation of Slayback’s Proposed NDA Product for at least the reasons set forth in the Detailed Statement of Slayback’s Notice Letter, dated June 1, 2023, which

has previously been served on Plaintiff.

76. Actual and justiciable controversies exist between Plaintiff and Slayback regarding the infringement of the '713 Patent.

77. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, Slayback requests a declaration from the Court that the manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product does not infringe the claims of the '713 Patent.

COUNTERCLAIM VI
(Declaratory Judgment of Invalidity of the '713 Patent)

78. Slayback repeats and realleges the allegations contained in Paragraphs 1 - 77 of its Counterclaims as if fully set forth herein.

79. This counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

80. This counterclaim is for a declaration that each and every claim of the '713 Patent is invalid for obviousness because it fails to satisfy the requirements of 35 U.S.C. § 103.

81. The claims of the '713 Patent are directed, *inter alia*, to a method of treating moderate to severe pain in an adult in need thereof comprising: administering once a day an intravenous bolus injection of a meloxicam formulation to achieve a mean AUC_{inf} of 107508.7±34443.0 ng*hr/ml in the adult, wherein the meloxicam formulation consists of 30 mg of nanoparticulate meloxicam, water, a surface stabilizer and a pharmaceutically acceptable excipient, wherein the nanoparticulate meloxicam has an effective average particle size of less than about 150 nm, wherein the meloxicam formulation comprises no more than 6,000 meloxicam particles that are greater than 10 μm in size and no more than 600 meloxicam particles that are

greater than 25 μm in size; and wherein the surface stabilizer is adsorbed on the surface of the nanoparticulate meloxicam and is essentially free of intermolecular cross-linkages.

82. Prior art U.S. Patent Publication No. 2004/0229038A1 ("the '038 publication") discloses a nanoparticulate meloxicam injectable formulation containing a surface stabilizer and the utility of meloxicam for the treatment of pain. The '038 publication further discloses that administration of meloxicam nanosuspensions to dogs resulted in AUC value of 118,225 ng.h/mL and 106,642 ng.h/mL.

83. Narjes discloses intramuscular injections with 30 mg meloxicam. Busch et al., *Eur J Clin Pharmacol* 1995, 48, 269-272 ("Busch") reports AUC_{∞} value of 5,200 ng.h/mL upon administration of a single 30 mg/mL i.v. injection of meloxicam to male individuals.

84. Prior art Toshiaki Sendo, *Acad Radiol.* 1998, 5, 444-447 ("Sendo") teaches that for small-volume parenteral preparations (<100 mL), the U.S. Pharmacopoeia provides limits of sub-visible particles based on the diameter of the particles. The limits allowed by the U.S. Pharmacopoeia for particles with diameters of ≥10 μm and ≥25 μm are 6,000 and 600 per container, respectively.

85. Accordingly, the claims of the '713 patent are invalid under 35 U.S.C. § 103 because the alleged invention described by the claims is obvious to a POSA in view of the prior art, including, but not limited to the art mentioned above.

86. Slayback reserves the right to provide additional bases for invalidity or unenforceability of the '713 Patent in its contentions, responses to discovery requests, expert reports and/or pleadings filed and/or served as this action progresses.

87. Actual and justiciable controversies exist between Plaintiff and Slayback regarding the validity and enforceability of the '713 Patent.

88. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, Slayback requests a declaration from the Court that each claim of the '713 Patent is invalid.

COUNTERCLAIM VII
(Declaratory Judgment of Non-Infringement of the '663 Patent)

89. Slayback repeats and realleges the allegations contained in Paragraphs 1 - 88 of its Counterclaims as if fully set forth herein.

90. This counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

91. In its Complaint, Plaintiff asserts that Slayback has infringed the '663 Patent by Slayback's submission of NDA No. 218395 to the FDA seeking to obtain approval for the manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product.

92. This counterclaim is for a declaration that Slayback has not infringed, induced infringement or contributed to the infringement, does not infringe, induce infringement or contribute to infringement through submission of Slayback's NDA, and will not infringe, induce infringement or contribute to infringement, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product of any valid and enforceable claim of the '663 Patent.

93. Plaintiff maintains, and Slayback denies, that Slayback's Proposed NDA Product will infringe the '663 Patent.

94. No claim of the '663 Patent is infringed or will be infringed by the manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product for at least the reasons set forth in the Detailed Statement of Slayback's Notice Letter, dated June 1, 2023, which has previously been served on Plaintiff.

95. Actual and justiciable controversies exist between Plaintiff and Slayback regarding the infringement of the '663 Patent.

96. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq*., Slayback requests a declaration from the Court that the manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product does not infringe the claims of the '663 Patent.

COUNTERCLAIM VIII
(Declaratory Judgment of Invalidity of the '663 Patent)

97. Slayback repeats and realleges the allegations contained in Paragraphs 1 - 96 of its Counterclaims as if fully set forth herein.

98. This counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

99. This counterclaim is for a declaration that each and every claim of the '663 Patent is invalid for obviousness because it fails to satisfy the requirements of 35 U.S.C. § 103.

100. The claims of the '663 Patent are directed, *inter alia*, to a method of treating pain, comprising administering to a patient meloxicam intravenously at a dose of about 30 mg, wherein the patient is at least 65 years old and has mild renal impairment, and wherein administration of meloxicam at the dose of about 30 mg is safe and well tolerated with no clinically meaningful differences between the patient and subjects aged 18 to 55 years with normal renal function (GFR>90 mL/min/1.73 m^2), and the meloxicam is present as meloxicam nanocrystals.

101. R. Mack et al., *The Journal of Pain* 2016, 17 (Suppl. 1), S77, Abstract#409 ("Mack") discloses a randomized, double-blind, placebo-controlled clinical trial that involved administration of an intravenous formulation of meloxicam nanocrystals to female subjects, undergoing open abdominal hysterectomy, for the management of moderate to severe pain. The

study involved administration of 30 mg of meloxicam nanocrystals and had subjects between the ages of 25-65 years.

102. In addition, it was known in the prior art that for patients with mild renal impairment no dose-adjustment of meloxicam would be needed as the pharmacokinetics parameters of meloxicam were not appreciably modified in such patient population as compared to younger patients with normal renal function. *See e.g.*, Neal M. Davies *et al., Clin Pharmacokinet* 1999, 36, 115-126 ("Davies") and P. J. R. Bevis *et al., Br J of Rheumat* 1996, 35 (suppl. 1), 56-60 ("Bevis").

103. Therefore, the claims of the '663 Patent are invalid under 35 U.S.C. § 103 because the alleged invention described by the claims is obvious to a POSA in view of the prior art, including, but not limited to the art mentioned above.

104. Slayback reserves the right to provide additional bases for invalidity or unenforceability of the '663 Patent in its contentions, responses to discovery requests, expert reports and/or pleadings filed and/or served as this action progresses.

105. Actual and justiciable controversies exist between Plaintiff and Slayback regarding the validity and enforceability of the '663 Patent.

106. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, Slayback requests a declaration from the Court that each claim of the '663 Patent is invalid.

COUNTERCLAIM IX
(Declaratory Judgment of Non-Infringement of the '145 Patent)

107. Slayback repeats and realleges the allegations contained in Paragraphs 1 - 106 of its Counterclaims as if fully set forth herein.

108. This counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This court has subject

matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

109. In its Complaint, Plaintiff asserts that Slayback has infringed the '145 Patent by Slayback's submission of NDA No. 218395 to the FDA seeking to obtain approval for the manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product.

110. This counterclaim is for a declaration that Slayback has not infringed, induced infringement or contributed to the infringement, does not infringe, induce infringement or contribute to infringement through submission of Slayback's NDA, and will not infringe, induce infringement or contribute to infringement, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product of any valid and enforceable claim of the '145 Patent.

111. Plaintiff maintains, and Slayback denies, that Slayback's Proposed NDA Product will infringe the '145 Patent.

112. No claim of the '145 Patent is infringed or will be infringed by the manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product for at least the reasons set forth in the Detailed Statement of Slayback's Notice Letter, dated June 1, 2023, which has previously been served on Plaintiff.

113. Actual and justiciable controversies exist between Plaintiff and Slayback regarding the infringement of the '145 Patent.

114. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, Slayback requests a declaration from the Court that manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product does not infringe the claims of the '145 Patent.

COUNTERCLAIM X
(Declaratory Judgment of Invalidity of the '145 Patent)

115. Slayback repeats and realleges the allegations contained in Paragraphs 1 - 114 of its Counterclaims as if fully set forth herein.

116. This counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

117. This counterclaim is for a declaration that each and every claim of the '145 Patent is invalid for obviousness because it fails to satisfy the requirements of 35 U.S.C. § 103.

118. The claims of the '145 Patent are directed, *inter alia*, to a method of treating moderate to severe pain in an adult patient with meloxicam, comprising administering intravenously once a day a first bolus dose of about 1 mL of a 30 mg/mL meloxicam nanocrystal aqueous dispersion; and further comprising administering intravenously a repeat bolus dose of about 1 mL of a 30 mg/mL meloxicam nanocrystal aqueous dispersion to the adult human patient about every 24 hours subsequent to the first dose; wherein the adult human patient has a reduction in summed pain intensity difference and a reduction in rescue analgesic use 48 hours after administration of the first bolus dose, and the repeat bolus dose; and wherein each of the bolus dose of about 1 mL of a 30 mg/mL meloxicam nanocrystal aqueous dispersion consists of 30 mg meloxicam nanocrystals, povidone, sodium deoxycholate, an excipient, and water.

119. U.S. Patent Publication No. 2010/0297252 discloses a meloxicam nanocrystal injectable dispersion containing polyvinylpyrrolidone, sodium deoxycholate and sucrose solution.

120. Mack discloses a placebo-controlled clinical trial involving administration of an intravenous formulation of 5, 7.5, 15, 30, or 60 mg of meloxicam nanocrystals to subjects, undergoing open abdominal hysterectomy, for the management of moderate to severe pain. Mack

reports that the greatest summed pain intensity difference was observed for the 30 and 60 mg groups and rescue medication use was lower in all meloxicam groups compared to placebo.

121. Likewise, R. Pollack *et al*., *The Journal of* Pain 2017 (April), *18 (Suppl. 1)*, S72, Abstract#391 ("Pollack") discloses administration of an intravenous formulation of 30 mg of meloxicam nanocrystals to subjects with moderate to severe pain following bunionectomy surgery. Subjects received 30 mg of meloxicam nanocrystal or placebo via i.v. every 24 hours for up to three doses. There was statistically significant reduction in the (i) summed pain intensity difference through 48 hours following the first dose and (ii) time to first use of rescue medication.

122. Therefore, the claims of the '145 Patent are invalid under 35 U.S.C. § 103 because the alleged invention described by the claims is obvious to a POSA in view of the prior art, including, but not limited to the art mentioned above.

123. Slayback reserves the right to provide additional bases for invalidity or unenforceability of the '145 Patent in its contentions, responses to discovery requests, expert reports and/or pleadings filed and/or served as this action progresses.

124. Actual and justiciable controversies exist between Plaintiff and Slayback regarding the validity and enforceability of the '145 Patent.

125. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq*., Slayback requests a declaration from the Court that each claim of the '145 Patent is invalid.

COUNTERCLAIM XI
(Declaratory Judgment of Non-Infringement of the '746 Patent)

126. Slayback repeats and realleges the allegations contained in Paragraphs 1 - 125 of its Counterclaims as if fully set forth herein.

127. This counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This court has subject

matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

128. In Slayback's Notice Letter, Slayback certified that Slayback's submission of NDA No. 218395 to the FDA seeking to obtain approval for the manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product would not infringe any valid or enforceable claim of the '746 Patent.

129. This counterclaim is for a declaration that Slayback has not infringed, induced infringement or contributed to the infringement, does not infringe, induce infringement or contribute to infringement through submission of Slayback's NDA, and will not infringe, induce infringement or contribute to infringement, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product of any valid and enforceable claim of the '746 Patent.

130. Slayback's Proposed NDA Product will not infringe the '746 Patent.

131. No claim of the '746 Patent is infringed or will be infringed by the manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product for at least the reasons set forth in the Detailed Statement of Slayback's Notice Letter, dated June 1, 2023, which has previously been served on Plaintiff.

132. Actual and justiciable controversies exist between Plaintiff and Slayback regarding the infringement of the '746 Patent.

133. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, Slayback requests a declaration from the Court that the manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product does not infringe the claims of the '746 Patent.

COUNTERCLAIM XII
(Declaratory Judgment of Invalidity of the '746 Patent)

134. Slayback repeats and realleges the allegations contained in Paragraphs 1 - 133 of its Counterclaims as if fully set forth herein.

135. This counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

136. This counterclaim is for a declaration that each and every claim of the '746 Patent is invalid for obviousness because it fails to satisfy the requirements of 35 U.S.C. § 103.

137. The claims of the '746 Patent are directed to, *inter alia*, to an injectable nanoparticulate active agent composition produced by a method for reducing flake-like aggregates, wherein the method comprises (a) preparing a dispersion of a nanoparticulate active agent and at least one surface stabilizer, wherein the dispersion comprises a nanoparticulate active agent having an effective average particle size of less than about 2000 nm, at least one surface stabilizer, and a liquid in which the active agent is poorly soluble; and (b) adding a flake-like aggregation reducing agent to the nanoparticulate active agent dispersion of step (a) to produce an injectable nanoparticulate active agent composition, wherein the flake-like aggregation reducing agent is selected from (i) a buffer selected from the group consisting of a phosphate buffer, an acetate buffer, a citrate buffer, a sodium phosphate buffer, a potassium phosphate buffer, and a sodium acetate buffer resulting in the composition having a pH above about 7.0, and (ii) a sugar selected from the group consisting of sucrose mannitol and dextrose, wherein the composition comprises no more than 6,000 active agent particles that are greater than 10 μm in size and no more than 600 active agent particles that are greater than 25 μm in size.

138. Prior art articles Combe and Narjes disclose intramuscular injections of meloxicam

and mention that the injectable formulations demonstrated more beneficial pharmacokinetic properties than an oral dosage form because of faster onset of action.

139. Prior art Mobic Package Insert, Boehringer Ingelheim Pharmaceuticals, Inc., 2000 discloses meloxicam has poor aqueous solubility.

140. The ’719 publication discloses drugs with low solubility in water can have significant benefits when formulated as a suspension of sub-micron particles and the particles must be small enough in diameter to safely pass through the capillaries of the patient.

141. The ’684 patent discloses that the rate of dissolution of a particulate drug can increase with increasing surface area, *i.e.*, decreasing particle size, and the particles should not flocculate or agglomerate. The ’684 patent, along with the ‘401 patent and the ‘864 patent further teach the utility of surface modifiers and other stabilizing excipients such as polyvinylpyrrolidone, sodium deoxycholate, and sucrose in such injectable nanoparticulate formulations. The ’684 patent states that the particle sizes of such nanoparticulate suspension are in the range of 3 nm - 400 nm.

142. Prior art Sendo teaches that for small-volume parenteral preparations (<100 mL), the U.S. Pharmacopoeia provides limits of sub-visible particles based on the diameter of the particles. The limits allowed by the U.S. Pharmacopoeia for particles with diameters of ≥10 µm and ≥25 µm are 6,000 and 600 per container, respectively.

143. Therefore, the claims of the ’746 Patent are invalid under 35 U.S.C. § 103 because the alleged invention described by the claims is obvious to a POSA in view of the prior art, including, but not limited to the art mentioned above.

144. Slayback reserves the right to provide additional bases for invalidity or unenforceability of the ’746 Patent in its contentions, responses to discovery requests, expert

reports and/or pleadings filed and/or served as this action progresses.

145. Actual and justiciable controversies exist between Plaintiff and Slayback regarding the validity and enforceability of the ’746 Patent.

146. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, Slayback requests a declaration from the Court that each claim of the ’746 Patent is invalid.

COUNTERCLAIM XIII
(Declaratory Judgment of Non-Infringement of the ’478 Patent)

147. Slayback repeats and realleges the allegations contained in Paragraphs 1 - 146 of its Counterclaims as if fully set forth herein.

148. This counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

149. In Slayback’s Notice Letter, Slayback certified that Slayback’s submission of NDA No. 218395 to the FDA seeking to obtain approval for the manufacture, use, sale, offer for sale, or importation of Slayback’s Proposed NDA Product would not infringe any valid or enforceable claim of the ’478 Patent.

150. This counterclaim is for a declaration that Slayback has not infringed, induced infringement or contributed to the infringement, does not infringe, induce infringement or contribute to infringement through submission of Slayback’s NDA, and will not infringe, induce infringement or contribute to infringement, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, or importation of Slayback’s Proposed NDA Product of any valid and enforceable claim of the ’478 Patent.

151. Slayback’s Proposed NDA Product will not infringe the ’478 Patent.

152. No claim of the ’478 Patent is infringed or will be infringed by the manufacture,

use, sale, offer for sale, or importation of Slayback's Proposed NDA Product for at least the reasons set forth in the Detailed Statement of Slayback's Notice Letter, dated June 1, 2023, which has previously been served on Plaintiff.

153. Actual and justiciable controversies exist between Plaintiff and Slayback regarding the infringement of the '478 Patent.

154. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq*., Slayback requests a declaration from the Court that the manufacture, use, sale, offer for sale, or importation of Slayback's Proposed NDA Product does not infringe the claims of the '478 Patent.

COUNTERCLAIM XIV
(Declaratory Judgment of Invalidity of the '478 Patent)

155. Slayback repeats and realleges the allegations contained in Paragraphs 1 - 154 of its Counterclaims as if fully set forth herein.

156. This counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

157. This counterclaim is for a declaration that each and every claim of the '478 Patent is invalid for obviousness because it fails to satisfy the requirements of 35 U.S.C. § 103.

158. The claims of the '478 Patent are directed, *inter alia*, to an injectable, nanoparticulate meloxicam composition consisting of: (a) about 2.5% to about 5% (w/w) of meloxicam particles having an effective average particle size of less than about 400 nm; (b) about 0.5% to about 1.625% (w/w) of at least one non-crosslinked surface stabilizer adsorbed on the surface of the meloxicam particles; (c) about 1.25% to about 20% (w/w) of a flake-like aggregation reducing agent; wherein the flake-like aggregation reducing agent consists of sucrose; and (d) water; wherein the injectable, nanoparticulate meloxicam composition comprises no more

than 3,000 meloxicam particles that are greater than 10 µm in size and no more than 300 active meloxicam particles that are greater than 25 µm in size when measured in a nominal volume of 25 mL, and wherein meloxicam is the only active agent in the composition, and wherein the composition is stable and suitable for injection after storage for at least 3 months at 25° C.

159. The ’038 publication discloses a nanoparticulate meloxicam injectable formulation containing a surface stabilizer and sucrose, and the utility of meloxicam for the treatment of pain.

160. Narjes and Busch disclose administration of meloxicam injection to individuals.

161. The ’684 patent discloses that the rate of dissolution of a particulate drug can increase with increasing surface area, *i.e.*, decreasing particle size, and the particles should not flocculate or agglomerate. The ’684 patent, along with the ‘401 and ‘864 patents further teach the utility of surface modifiers and other stabilizing excipients such as sucrose in such injectable nanoparticulate formulations. The ’684 patent states that the particle sizes of such nanoparticulate suspension are in the range of 3 nm - 400 nm.

162. Prior art Sendo teaches that for small-volume parenteral preparations (<100 mL), the U.S. Pharmacopoeia provides limits of sub-visible particles based on the diameter of the particles. The limits allowed by the U.S. Pharmacopoeia for particles with diameters of ≥10 µm and ≥25 µm are 6,000 and 600 per container, respectively.

163. Therefore, the claims of the ’478 Patent are invalid under 35 U.S.C. § 103 because the alleged invention described by the claims is obvious to a POSA in view of the prior art, including, but not limited to the art mentioned above.

164. Slayback reserves the right to provide additional bases for invalidity or unenforceability of the ’478 Patent in its contentions, responses to discovery requests, expert reports and/or pleadings filed and/or served as this action progresses.

165. Actual and justiciable controversies exist between Plaintiff and Slayback regarding the validity and enforceability of the ’478 Patent.

166. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq*., Slayback requests a declaration from the Court that each claim of the ’478 Patent is invalid.

PRAYER FOR RELIEF

WHEREFORE, Slayback respectfully requests that this Court enter judgment in its favor and against Plaintiff as follows:

A. Dismissing the Complaint with prejudice, denying each and every Request for Relief contained therein, and ordering that Plaintiff take nothing thereby;

B. Declaring that the manufacture, use, sale, offer for sale, or importation of Slayback’s Proposed NDA Product described in Slayback’s NDA No. 218395 does not and will not infringe any valid and/or enforceable claim of the ’673 patent;

C. Declaring the claims of the ’673 patent invalid or unenforceable pursuant to 35 U.S.C. §§ 101, 102, 103, and/or 112;

D. Declaring that the manufacture, use, sale, offer for sale, or importation of Slayback’s Proposed NDA Product described in Slayback’s NDA No. 218395 does not and will not infringe any valid and/or enforceable claim of the ’067 patent;

E. Declaring the claims of the ’067 patent invalid or unenforceable pursuant to 35 U.S.C. §§ 101, 102, 103, and/or 112;

F. Declaring that the manufacture, use, sale, offer for sale, or importation of Slayback’s Proposed NDA Product described in Slayback’s NDA No. 218395 does not and will not infringe any valid and/or enforceable claim of the ’713 patent;

G. Declaring the claims of the ’713 patent invalid or unenforceable pursuant to 35 U.S.C. §§ 101, 102, 103, and/or 112;

H. Declaring that the manufacture, use, sale, offer for sale, or importation of Slayback’s Proposed NDA Product described in Slayback’s NDA No. 218395 does not and will not infringe any valid and/or enforceable claim of the ’663 patent;

I. Declaring the claims of the ’663 patent invalid or unenforceable pursuant to 35 U.S.C. §§ 101, 102, 103, and/or 112;

J. Declaring that the manufacture, use, sale, offer for sale, or importation of Slayback’s Proposed NDA Product described in Slayback’s NDA No. 218395 does not and will not infringe any valid and/or enforceable claim of the ’145 patent;

K. Declaring the claims of the ’145 patent invalid or unenforceable pursuant to 35 U.S.C. §§ 101, 102, 103, and/or 112;

L. Declaring that the manufacture, use, sale, offer for sale, or importation of Slayback’s Proposed NDA Product described in Slayback’s NDA No. 218395 does not and will not infringe any valid and/or enforceable claim of the ’746 patent;

M. Declaring the claims of the ’746 patent invalid or unenforceable pursuant to 35 U.S.C. §§ 101, 102, 103, and/or 112;

N. Declaring that the manufacture, use, sale, offer for sale, or importation of Slayback’s Proposed NDA Product described in Slayback’s NDA No. 218395 does not and will not infringe any valid and/or enforceable claim of the ’478 patent;

O. Declaring that the claims of the ’478 patent invalid or unenforceable pursuant to 35 U.S.C. § 101, 102, 103, and/or 112;

P. Permanently enjoining Plaintiff or any of its assignees or successors from asserting that the commercial manufacture, use, sale, offer for sale, or importation of Slayback’s Proposed NDA Product described in Slayback’s NDA No. 218395 infringes or will infringe any claim of the Orange Book Patents;

Q. Awarding Slayback its costs and expenses in this action;

R. Declaring that this is an exceptional case under 35 U.S.C. §285 and/or other applicable laws and awarding Slayback its attorneys’ fees, costs and expenses in this action;

S. An order allowing Slayback to launch its Proposed NDA Product, if it chooses to do so, upon FDA approval; and

T. Awarding Slayback such further relief this Court may deem just and proper.

Dated: October 27, 2023

s/ Andrew J. Miller
Andrew J. Miller
WINDELS MARX LANE & MITTENDORF, LLP
One Giralda Farms
Madison, NJ 07940
(973) 966-3200
amiller@windelsmarx.com

Attorney for Defendants Slayback Pharma LLC and Slayback Pharma India LLP

LOCAL CIVIL RULE 201.1 CERTIFICATION

Pursuant to Local Civil Rule 201.1, the undersigned attorney for Slayback hereby certifies that this action is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief against Slayback in Plaintiff's Complaint for Patent Infringement.

Dated: October 27, 2023

s/ Andrew J. Miller
Andrew J. Miller
WINDELS MARX LANE & MITTENDORF, LLP
One Giralda Farms
Madison, NJ 07940
(973) 966-3200
amiller@windelsmarx.com

Attorney for Defendants Slayback Pharma LLC and Slayback Pharma India LLP

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a true and accurate copy of the foregoing DEFENDANTS SLAYBACK PHARMA LLC AND SLAYBACK PHARMA INDIA LLP'S ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTECLAIMS caused to be filed with the Court's electronic filing system, and served on all counsel of record for Plaintiff via the Court's electronic filing system and electronic mail on October 27, 2023.

Dated: October 27, 2023

s/ Andrew J. Miller
Andrew J. Miller