IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIFOR PHARMA, INC. AND VIFOR (INTERNATIONAL) LTD., Plaintiffs, v. ALKEM LABORATORIES LTD. and ASCENT PHARMACEUTICALS, INC., Defendants.	C.A. No. 1:20-cv-00106-MN

ALKEM LABORATORIES LTD.'S ANSWER, DEFENSES AND COUNTERCLAIMS

Defendant Alkem Laboratories Ltd. ("Alkem") hereby provides its Answer to the Second Amended Complaint of Vifor Pharma, Inc. ("Vifor Pharma") and Vifor (International) Ltd. ("Vifor Ltd.") (collectively, "Plaintiffs") as follows.

GENERAL DENIAL

Pursuant to Federal Rule of Civil Procedure 8(b)(3), Alkem denies all allegations in Plaintiffs' Second Amended Complaint (D.I. 128) except those specifically admitted below.

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 8,147,873, as extended by the Certificate Extending Patent Term that issued on December 17, 2019 ("the '873 patent"), 8,337,824, as corrected by the Certificate of Correction that issued on November 5, 2013 ("the '824 patent"), 9,492,476 ("the '476 patent"), 9,925,212 ("the '212 patent"), and 11,123,363, as corrected by the Certificate of Correction that issued on November 16, 2021 ("the '363 patent") (collectively, "the Patents-in-Suit"), under the laws of the United States, 35 U.S.C. § 100, *et seq.* arising from Alkem's and Ascent's filing of Abbreviated New Drug Applications ("ANDAs") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Plaintiffs' VELTASSA® drug product prior to the expiration of the Patents-in-Suit.

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that this is an action for alleged infringement of United States Patent Nos. 8,147,873 ("the '873 patent"), 8,337,824 ("the '824 patent"), 9,492,476 ("the '476 patent"), 9,925,212 ("the '212 patent"), and 11,123,363 ("the '363 patent") (collectively, "the Patents-in-Suit"). Alkem further admits that Alkem submitted an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA"), seeking approval to engage in the commercial manufacture, use, or sale of patiromer powder for oral suspension, 8.4 g, 16.8 g and 25.2 g, prior to the expiration of the Patents-in-Suit. Alkem denies all remaining allegations of Paragraph 1.

THE PARTIES

2. Plaintiff Vifor Pharma is a corporation organized and existing under the laws of Delaware, with its principal place of business at 100 Cardinal Way, Redwood City, California 94063.

ANSWER: Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 2, and therefore denies the same.

3. Plaintiff Vifor Ltd. is a limited company organized and existing under the laws of Switzerland, with its principal place of business at Rechenstraße 37, St. Gallen, 9000, Switzerland.

ANSWER: Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 3, and therefore denies the same.

4. On information and belief, defendant Alkem is a limited company organized and existing under the laws of India, with a principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai - 400 013, India.

ANSWER: Paragraph 4 contains legal conclusions to which no answer is required. To the extent that an answer is required, Alkem admits that Alkem is a corporation operating and existing solely under the laws of India, having its head office at Devashish Building, Alkem House,

Senapati Bapat Road, Lower Parel, Mumbai, 400 013, India. Alkem denies all remaining allegations of Paragraph 4.

5. On information and belief, defendant Ascent is a corporation organized and existing under the laws of New York, with a principal place of business at 400 South Technology Drive, Central Islip, NY 11722.

ANSWER: The allegations of Paragraph 5 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 5, and therefore denies all allegations of Paragraph 5.

THE PATENTS-IN-SUIT

6. On April 3, 2012, the United States Patent and Trademark Office ("USPTO") issued U.S. Patent No. 8,147,873, entitled "Methods and Compositions for Treatment of Ion Imbalances." The inventors of the '873 patent are Dominique Charmot and Mingjun Liu. Vifor Ltd. is the assignee of the '873 patent. A copy of the '873 patent, including the Certificate Extending Patent Term, is attached hereto as Exhibit A.

ANSWER: Paragraph 6 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that, according to the electronic records of the United States Patent and Trademark Office ("USPTO"), the '873 patent, titled "METHODS AND COMPOSITIONS FOR TREATMENT OF ION IMBALANCES," issued on April 3, 2012. Alkem further admits that the '873 patent purports to name Dominique Charmot and Mingjun Liu as the alleged inventors of the '873 patent. Alkem further admits that, according to the online records of the USPTO, the '873 patent is purportedly assigned to Vifor Ltd. Alkem further admits that what purports to be a copy of the '873 patent is attached to Plaintiffs' Amended Complaint as Exhibit A. Alkem denies any suggestion or implication that the '873 patent is valid or enforceable. Alkem denies all remaining allegations of Paragraph 6.

7. On December 25, 2012, the USPTO issued U.S. Patent No. 8,337,824, entitled "Linear Polyol Stabilized Polyfluoroacrylate Compositions." The inventors of the '824 patent are Detlef Albrecht, Michael Burdick, Han-Ting Chang, Dominique Charmot, Ramakrishnan

Chidambaram, Eric Connor, Sherin Halfon, I-Zu Huang, Mingjun Liu, Jonathan Mills, and Werner Strüver. Vifor Ltd. is the assignee of the '824 patent. A copy of the '824 patent, as corrected by the Certificate of Correction, is attached hereto as Exhibit B.

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that, according to the electronic records of the USPTO, the '824 patent, titled "LINEAR POLYOL STABILIZED POLYFLUOROACRYLATE COMPOSITIONS," issued on December 25, 2012. Alkem further admits that the '824 patent purports to name Detlef Albrecht, Michael Burdick, Han-Ting Chang, Dominique Charmot, Ramakrishnan Chidambaram, Eric Connor, Sherin Halfon, I-Zu Huang, Mingjun Liu, Jonathan Mills, and Werner Strüver as the alleged inventors of the '824 patent. Alkem further admits that, according to the online records of the USPTO, the '824 patent is purportedly assigned to Vifor Ltd. Alkem further admits that what purports to be a copy of the '824 patent is attached to Plaintiffs' Amended Complaint as Exhibit B. Alkem denies any suggestion or implication that the '824 patent is valid or enforceable. Alkem denies all remaining allegations of Paragraph 7.

8. On November 15, 2016, the USPTO issued U.S. Patent No. 9,492,476, entitled "Potassium-Binding Agents for Treating Hypertension and Hyperkalemia." The inventors of the '476 patent are Gerrit Klaerner and Lance Berman. Vifor Ltd. is the assignee of the '476 patent. A copy of the '476 patent is attached hereto as Exhibit C.

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that, according to the electronic records of the USPTO, the '476 patent, titled "POTASSIUM-BINDING AGENTS FOR TREATING HYPERTENSION AND HYPERKALEMIA," issued on November 15, 2016. Alkem further admits that the '476 patent purports to name Gerrit Klaerner and Lance Berman as the alleged inventors of the '476 patent. Alkem further admits that, according to the online records of the USPTO, the '476 patent is purportedly assigned to Vifor Ltd. Alkem further admits that what purports to be a copy of the '476 patent is attached to Plaintiffs' Amended Complaint as Exhibit

C. Alkem denies any suggestion or implication that the '476 patent is valid or enforceable. Alkem denies all remaining allegations of Paragraph 8.

9. On March 27, 2018, the USPTO issued U.S. Patent No. 9,925,212, entitled "Potassium-Binding Agents for Treating Hypertension and Hyperkalemia." The inventors of the '212 patent are Gerrit Klaerner and Lance Berman. Vifor Ltd. is the assignee of the '212 patent. A copy of the '212 patent is attached hereto as Exhibit D.

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that, according to the electronic records of the USPTO, the '212 patent, titled "POTASSIUM-BINDING AGENTS FOR TREATING HYPERTENSION AND HYPERKALEMIA," issued on March 27, 2018. Alkem further admits that the '212 patent purports to name Gerrit Klaerner and Lance Berman as the alleged inventors of the '212 patent. Alkem further admits that, according to the online records of the USPTO, the '212 patent is purportedly assigned to Vifor Ltd. Alkem further admits that what purports to be a copy of the '212 patent is attached to Plaintiffs' Amended Complaint as Exhibit D. Alkem denies any suggestion or implication that the '212 patent is valid or enforceable. Alkem denies all remaining allegations of Paragraph 9.

10. On September 21, 2021, the USPTO issued U.S. Patent No. 11,123,363, entitled "Potassium-Binding Agents for Treating Hypertension and Hyperkalemia." The inventors of the '363 patent are Gerrit Klaerner and Lance Berman. Vifor Ltd. is the assignee of the '363 patent. A copy of the '363 patent, as corrected by its Certificate of Correction, is attached hereto as Exhibit E.

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that, according to the electronic records of the USPTO, the '363 patent, titled "POTASSIUM-BINDING AGENTS FOR TREATING HYPERTENSION AND HYPERKALEMIA," issued on September 21, 2021. Alkem further admits that the '363 patent purports to name Gerrit Klaerner and Lance Berman as the alleged inventors of the '363 patent. Alkem further admits that, according to the online records of the

USPTO, the '363 patent is purportedly assigned to Vifor Ltd. Alkem further admits that what purports to be a copy of the '363 patent is attached to Plaintiffs' Second Amended Complaint as Exhibit E. Alkem denies any suggestion or implication that the '363 patent is valid or enforceable. Alkem denies all remaining allegations of Paragraph 10.

THE VELTASSA® DRUG PRODUCT

11. Vifor Pharma holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for patiromer sorbitex calcium powder for oral suspension in three strengths, an 8.4 gram base/packet, a 16.8 gram base/packet, and a 25.2 gram base/packet (NDA No. 205739), sold under the trade name VELTASSA®. VELTASSA® is a potassium binder indicated for the treatment of hyperkalemia. Vifor Pharma received approval for VELTASSA® from the FDA in October 2015.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem states that the electronic version of FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), identifies "VIFOR PHARMA INC" as the "Applicant Holder" for New Drug Application ("NDA") No. 205739 for VELTASSA® (PATIROMER SORBITEX CALCIUM) powder, 8.4 g base/packet, 16.8 g base/packet, and 25.2 g base/packet. Alkem denies all remaining allegations of Paragraph 11.

12. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the Patents-in-Suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), in connection with VELTASSA®.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the Orange Book identifies the Patents-in-Suit in connection with NDA No. 205739 for VELTASSA® (PATIROMER SORBITEX CALCIUM) powder. Alkem denies all remaining allegations of Paragraph 12.

ACTS GIVING RISE TO THIS ACTION

13. On information and belief, Alkem submitted Abbreviated New Drug Application No. 214075 (the "Alkem ANDA") to the FDA under § 505(j) of the FFDCA (21 U.S.C. § 355(j)).

On information and belief, the Alkem ANDA seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of patiromer sorbitex calcium powder for oral suspension in three strengths, 8.4 gram base/packet, 16.8 gram base/packet, and 25.2 gram base/packet ("Alkem Proposed ANDA Product"), as generic versions of VELTASSA®. The Alkem ANDA specifically seeks FDA approval to market the Alkem Proposed ANDA Product prior to the expiration of the '873, '824, '476, and '212 patents.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that Alkem submitted an ANDA to the FDA, seeking approval to engage in the manufacture, use, sale, offer for sale and/or importation of patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g, and identifying VELTASA® (patiromer sorbitex calcium) powder as the reference listed product. Alkem further admits that Alkem's ANDA contains a certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, as amended, ("FDCA") seeking approval for patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g, prior to the expiration of the Patents-in-Suit. Alkem denies all remaining allegations of Paragraph 13.

14. On information and belief, following any FDA approval of the Alkem ANDA, Alkem will make, use, offer to sell, and/or sell the Alkem Proposed ANDA Product throughout the United States, and/or import such generic products into the United States.

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that Alkem submitted an ANDA to the FDA, seeking approval to engage in the manufacture, use, sale, offer for sale and/or importation of patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g. Alkem denies all remaining allegations of Paragraph 14.

15. On or about December 20, 2019, Plaintiffs received a letter dated December 19, 2019 from Alkem's counsel ("Alkem's Paragraph IV Certification Letter") stating that the Alkem ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Alkem's Paragraph IV Certification"), which provides that, in Alkem's opinion, the claims of the '873, '824, '476, and '212 patents are invalid and/or will not be infringed by the commercial manufacture, use, sale, offer for sale and/or importation of the Alkem Proposed ANDA Product.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that in a Notification dated December 19, 2019, Alkem provided requisite notice to Relypsa, Inc. and Vifor (International) Ltd. that Alkem filed an ANDA with the FDA seeking approval for patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g. Alkem further admits that Alkem's ANDA contains a certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the FDCA seeking approval for patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g, prior to the expiration of the '873, '824, '476, and '212 patents. Alkem denies all remaining allegations of Paragraph 15.

16. This action was commenced on January 23, 2020 before the expiration of 45 days from the date Plaintiffs received Alkem's Paragraph IV Certification Letter.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the electronic court records of the United States District Court for the District of Delaware indicate that Plaintiffs filed the Complaint in this action on January 23, 2020. Alkem denies all remaining allegations of Paragraph 16.

17. On information and belief, Ascent submitted Abbreviated New Drug Application No. 214098 (the "Ascent ANDA") to the FDA under § 505(j) of the FFDCA (21 U.S.C. § 355(j)). On information and belief, the Ascent ANDA seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of patiromer sorbitex calcium powder for oral suspension in three strengths, 8.4 gram base/packet, 16.8 gram base/packet, and 25.2 gram base/packet ("Ascent Proposed ANDA Product"), as generic versions of VELTASSA®. The Ascent ANDA specifically seeks FDA approval to market the Ascent Proposed ANDA Product prior to the expiration of the '824, '476, and '212 patents.

ANSWER: The allegations of Paragraph 17 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 17, and therefore denies all allegations of Paragraph 17.

18. On information and belief, following any FDA approval of the Ascent ANDA, Ascent will make, use, offer to sell, and/or sell the Ascent Proposed ANDA Product throughout the United States, and/or import such generic products into the United States.

ANSWER: The allegations of Paragraph 18 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 18, and therefore denies all allegations of Paragraph 18.

19. On or about December 10, 2019, Plaintiffs received a letter dated December 9, 2019 from Ascent's counsel ("Ascent's December 9, 2019 Paragraph IV Certification Letter") stating that the Ascent ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which provides that, in Ascent's opinion, the claims of the '824, '476, and '212 patents are invalid and/or will not be infringed by the manufacture, use or sale of the Ascent Proposed ANDA Product.

ANSWER: The allegations of Paragraph 19 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 19, and therefore denies all allegations of Paragraph 19.

20. On or about July 8, 2020, Plaintiffs received a letter dated July 7, 2020 from Ascent's counsel ("Ascent's July 7, 2020 Paragraph IV Certification Letter") stating the Ascent ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which provides that, in Ascent's opinion, the claims of the '873 patent are invalid and/or will not be infringed by the manufacture, use or sale of the Ascent Proposed ANDA Product. The certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) contained in Ascent's letters dated December 9, 2019 and July 7, 2020 are collectively referred to herein as "Ascent's Paragraph IV Certification."

ANSWER: The allegations of Paragraph 20 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 20, and therefore denies all allegations of Paragraph 20.

21. This action was commenced on January 23, 2020 before the expiration of 45 days from the date Plaintiffs received Ascent's December 9, 2019 Paragraph IV Certification Letter. This action is being amended to include claims directed to Ascent's infringement of the '873 patent before the expiration of 45 days from the date Plaintiffs received Ascent's July 7, 2020 Paragraph IV Certification Letter.

ANSWER: The allegations of Paragraph 21 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information

sufficient to form a belief as to the truth of the allegations of Paragraph 21, and therefore denies all allegations of Paragraph 21.

JURISDICTION AND VENUE

22. This Court has subject matter jurisdiction over the matters asserted herein under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Alkem does not contest subject matter jurisdiction solely for the claims directed against it under 35 U.S.C. § 271(e)(2)(A) and solely for the limited purposes of this action only. Alkem denies that subject matter jurisdiction is proper for any purported claims asserted against Alkem under 35 U.S.C. § 271(a), (b) or (c). Alkem denies all remaining allegations of Paragraph 22.

23. This Court has personal jurisdiction over Alkem because, inter alia, Alkem has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in Delaware. For example, on information and belief, following approval of the Alkem ANDA, Alkem will make, use, offer for sale, sell, and/or import the Alkem Proposed ANDA Product in the United States, including in Delaware, prior to the expiration of the '873, '824, '476, '212, and '363 patents.

ANSWER: Paragraph 23 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Further answering, solely to conserve the resources of the parties and the Court, Alkem does not contest personal jurisdiction in this judicial District solely for the limited purposes of this action only with respect to the Patents-in-Suit. Alkem denies all remaining allegations of Paragraph 23.

24. This Court also has personal jurisdiction over Alkem because Alkem has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the State of Delaware. On information and belief, Alkem regularly and continuously transacts business within Delaware, including by marketing, distributing, and selling pharmaceutical products in Delaware. On information and belief, Alkem derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Further answering, solely to conserve the resources of the parties and the Court, Alkem does not contest personal jurisdiction in this judicial District solely for the limited purposes of this action only with respect to the Patents-in-Suit. Alkem denies all remaining allegations of Paragraph 24.

25. On information and belief, Alkem has continuously placed its products into the stream of commerce for distribution and consumption in the State of Delaware, and throughout the United States, and thus has engaged in the regular conduct of business within this Judicial District.

ANSWER: Paragraph 25 contains legal conclusions to which no answer is required. To the extent that an answer is required, Alkem admits that Alkem develops, manufactures, markets and sells pharmaceutical products, including quality generic medicines. Alkem denies all remaining allegations of Paragraph 25.

26. On information and belief, Alkem derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this Judicial District.

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent that an answer is required, Alkem admits that Alkem develops, manufactures, markets and sells pharmaceutical products, including quality generic medicines. Alkem denies all remaining allegations of Paragraph 26.

27. On information and belief, Alkem has previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in prior patent cases. On information and belief, Alkem has been sued for patent infringement in this District and did not contest personal jurisdiction in this District in, for example, the following cases: *H. Lundbeck A/S, et al. v. Alkem Laboratories Ltd. and S&B Pharma, Inc.,* C.A. No. 18-89-LPS (D. Del.); *Takeda Pharmaceuticals U.S.A., Inc. v. Alkem Laboratories Ltd. and Ascend Laboratories, LLC,* C.A. No. 18-189-RGA (D. Del.); *Teijin Ltd. et al. v. Alkem Laboratories Ltd. and Ascend Laboratories, LLC,* C.A. No. 19-768-RGA (D. Del.); and *Bial-Portela & CA S.A., et al. v. Alkem Laboratories Ltd. and S&B Pharma, Inc.,* C.A. No. 18-304-VAC-MPT (D. Del.).

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that Alkem has been sued in this judicial District. Alkem denies all remaining allegations of Paragraph 27.

28. Additionally, on information and belief, Alkem has availed itself of the benefits of this forum through assertions of counterclaims in suits brought in this district, such as: *H. Lundbeck A/S, et al. v. Alkem Laboratories Ltd. and S&B Pharma, Inc.,* C.A. No. 18-89-LPS (D. Del.); and *Bial-Portela & CA S.A., et al. v. Alkem Laboratories Ltd. and S&B Pharma, Inc.,* C.A. No. 18-304-VAC-MPT (D. Del.).

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that Alkem has asserted counterclaims in this judicial District. Alkem denies all remaining allegations of Paragraph 28.

29. In the alternative, this Court has jurisdiction over Alkem because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Alkem's claims arise under federal law; (b) Alkem is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Alkem has sufficient contacts with the United States as a whole, including, but not limited to, participating in the preparation and submission of the Alkem ANDA for the Alkem Proposed ANDA Product to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Alkem satisfies due process.

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Further answering, solely to conserve the resources of the parties and the Court, Alkem does not contest personal jurisdiction in this judicial District solely for the limited purposes of this action only with respect to the Patents-in-Suit. Alkem denies all remaining allegations of Paragraph 29.

30. Venue is proper for Alkem under 28 U.S.C. §§ 1391 and/or 1400(b), including because, *inter alia*, Alkem is a foreign corporation and is subject to personal jurisdiction in this Judicial District, as set forth above. In addition, Alkem has committed an act of infringement and will commit further acts of infringement in this Judicial District, as set forth in paragraph 23 above, and continuously transacts business in this Judicial District, as set forth in paragraphs 24–26 above.

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Further answering, solely to conserve the resources of

the parties and the Court, Alkem does not contest venue in this judicial District solely for the limited purposes of this action only with respect to the Patents-in-Suit. Alkem denies all remaining allegations of Paragraph 30.

31. This Court has personal jurisdiction over Ascent because, inter alia, Ascent has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in Delaware. For example, on information and belief, following approval of the Ascent ANDA, Ascent will make, use, offer for sale, sell, and/or import the Ascent Proposed ANDA Product in the United States, including in Delaware, prior to the expiration of the '873, '824, '476, '212, and '363 patents.

ANSWER: The allegations of Paragraph 31 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 31, and therefore denies all allegations of Paragraph 31.

32. This Court also has personal jurisdiction over Ascent because Ascent has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the State of Delaware. On information and belief, Ascent regularly and continuously transacts business within Delaware, including by marketing, distributing, and selling pharmaceutical products in Delaware. On information and belief, Ascent derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

ANSWER: The allegations of Paragraph 32 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 32, and therefore denies all allegations of Paragraph 32.

33. On information and belief, Ascent has continuously placed its products into the stream of commerce for distribution and consumption in the State of Delaware, and throughout the United States, and thus has engaged in the regular conduct of business within this Judicial District.

ANSWER: The allegations of Paragraph 33 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information

sufficient to form a belief as to the truth of the allegations of Paragraph 33, and therefore denies all allegations of Paragraph 33.

34. On information and belief, Ascent derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this Judicial District.

ANSWER: The allegations of Paragraph 34 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 34, and therefore denies all allegations of Paragraph 34.

35. Ascent's website indicates that it manufactures generic pharmaceuticals for its affiliate, Camber Pharmaceuticals, Inc. ("Camber"). *See* Ascent Product List, http://ascentpharm.com/products/dutastcamber/ (last visited January 20, 2020). On information and belief, Camber is a corporation organized and existing under the laws of the state of Delaware that shares the same parent company as Ascent. On information and belief, Camber sells generic pharmaceutical products, including those manufactured by Ascent, in the United States, including in Delaware.

ANSWER: The allegations of Paragraph 35 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 35, and therefore denies all allegations of Paragraph 35.

36. On information and belief, Ascent has previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in prior patent cases. On information and belief, Ascent has been sued for patent infringement in this District and did not contest personal jurisdiction in this District in, for example, the following cases: *Purdue Pharma L.P., et al. v. Ascent Pharmaceuticals, Inc.,* C.A. No. 18-83-RGA (D. Del.); and *Anacor Pharmaceuticals, Inc. v. Ascent Pharmaceuticals, Inc., et al.,* C.A. 18-1673-LPS (D. Del.).

ANSWER: The allegations of Paragraph 36 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 36, and therefore denies all allegations of Paragraph 36.

37. Additionally, on information and belief, Ascent has availed itself of the benefits of this forum through assertions of counterclaims in suits brought in this district, such as: *Purdue Pharma L.P., et al. v. Ascent Pharmaceuticals, Inc.,* C.A. No. 18-83-RGA (D. Del.); and *Anacor Pharmaceuticals, Inc. v. Ascent Pharmaceuticals, Inc., et al.,* C.A. 18-1673-LPS (D. Del.).

ANSWER: The allegations of Paragraph 37 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 37, and therefore denies all allegations of Paragraph 37.

38. Venue is proper for Ascent at least because Ascent's counsel has confirmed via email dated January 16, 2020, that Ascent consents to venue in Delaware for purposes of this case only.

ANSWER: The allegations of Paragraph 38 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 38, and therefore denies all allegations of Paragraph 38.

COUNT I: THE '873 PATENT BY ALKEM

39. Plaintiffs repeat and reallege paragraphs 1-38 above as if fully set forth herein.

ANSWER: Alkem restates and incorporates by reference each of its answers in Paragraphs 1-38, as if fully set forth herein.

40. By filing the Alkem ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Alkem Proposed ANDA Product before the expiration of the '873 patent, Alkem committed an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

41. Moreover, if Alkem commercially makes, uses, offers to sell, or sells the Alkem Proposed ANDA Product within the United States, or imports the Alkem Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '873 patent, Alkem will further infringe the '873 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

42. Upon information and belief, the Alkem Proposed ANDA Product includes the active ingredient patiromer sorbitex calcium and claims bioequivalence to VELTASSA®. Accordingly, the Alkem Proposed ANDA Product infringes at least claim 1 of the '873 patent.

ANSWER: Paragraph 42 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that Alkem submitted an ANDA seeking approval for patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g. Alkem further admits it has otherwise satisfied all statutory and regulatory requirements relating to its ANDA submission, including to show that its generic drug is "bioequivalent" to the reference listed drug. Alkem denies all remaining allegations of Paragraph 42.

43. Alkem has infringed at least claim 1 of the '873 patent under 35 U.S.C. § 271(e)(2) and, upon approval of Alkem's Proposed ANDA Product, will further infringe at least that claim under 35 U.S.C. §§ 271(a), (b), and/or (c) because the Alkem Proposed ANDA Product and the methods of using the Alkem Proposed ANDA Product, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the proposed package insert will meet each and every claim element of at least claim 1 of the '873 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

44. Alkem has had knowledge of the '873 patent since at least the date Alkem submitted the Alkem ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2). Alkem has had knowledge of the '873 patent by at least the date of service of this Complaint. Alkem's actions render this an exceptional case under 35 U.S.C. § 285.

ANSWER: Paragraph 44 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem states that, as required under Section 505(j)(2)(A)(vii), Alkem included a certification to each patent listed in the Orange Book in connection with the Reference Listed Drug, VELTASSA®, NDA No. 205739, at the time of its ANDA submission. Alkem further admits that Alkem's ANDA contains a certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the FDCA seeking approval for patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g, prior to the expiration of the '873 patent, which patent was listed in the

Orange Book at the time of that ANDA submission. Alkem denies all remaining allegations of Paragraph 44.

45. Upon information and belief, Alkem has knowledge that if it were to receive approval from the FDA to market the Alkem Proposed ANDA Product and made that product available for sale and/or use by others, *e.g.*, by doctors, pharmacists, healthcare providers and patients, during the proposed shelf life of the products before expiration of the '873 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. Upon information and belief, Alkem has knowledge of such infringing use and also knows that the Alkem Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '873 patent.

ANSWER: Denied.

46. Upon information and belief, Alkem was aware of the '873 patent prior to filing the Alkem ANDA, including its Paragraph IV Certification allegations with respect to those patents. Upon information and belief, the proposed label for the Alkem Proposed ANDA Product induces others, *e.g.*, doctors, pharmacists, healthcare providers and patients, to infringe the '873 patent, and based on Alkem's Paragraph IV Certification allegations, Alkem possesses the specific intent to encourage others to infringe.

ANSWER: Paragraph 46 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem states that, as required under Section 505(j)(2)(A)(vii), Alkem included a certification to each patent listed in the Orange Book in connection with the Reference Listed Drug, VELTASSA®, NDA No. 205739, at the time of its ANDA submission. Alkem further admits that Alkem's ANDA contains a certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the FDCA seeking approval for patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g, prior to the expiration of the '873 patent, which patent was listed in the Orange Book at the time of that ANDA submission. Alkem denies all remaining allegations of Paragraph 46.

47. Plaintiffs will be irreparably harmed if Alkem is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '873 patent. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT II: THE '824 PATENT BY ALKEM

48. Plaintiffs repeat and reallege paragraphs 1-47 above as if fully set forth herein.

ANSWER: Alkem restates and incorporates by reference each of its answers in Paragraphs 1-47, as if fully set forth herein.

49. By filing the Alkem ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Alkem Proposed ANDA Product before the expiration of the '824 patent, Alkem committed an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

50. Moreover, if Alkem commercially makes, uses, offers to sell, or sells the Alkem Proposed ANDA Product within the United States, or imports the Alkem Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '824 patent, Alkem will further infringe the '824 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

51. Upon information and belief, the Alkem Proposed ANDA Product includes the active ingredient patiromer sorbitex calcium and claims bioequivalence to VELTASSA®. Accordingly, the Alkem Proposed ANDA Product infringes at least claim 1 of the '824 patent.

ANSWER: Paragraph 51 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that Alkem submitted an ANDA seeking approval for patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g. Alkem further admits it has otherwise satisfied all statutory and regulatory requirements relating to its ANDA submission, including to show that its generic drug is "bioequivalent" to the reference listed drug. Alkem denies all remaining allegations of Paragraph 51.

52. Alkem has infringed at least claim 1 of the '824 patent under 35 U.S.C. § 271(e)(2) and, upon approval of Alkem's Proposed ANDA Product, will further infringe at least that claim under 35 U.S.C. §§ 271(a), (b), and/or (c) because the Alkem Proposed ANDA Product and the methods of using the Alkem Proposed ANDA Product, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the proposed package insert will meet each and every claim element of at least claim 1 of the '824 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

53. Alkem has had knowledge of the '824 patent since at least the date Alkem submitted the Alkem ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2). Alkem has had knowledge of the '824 patent by at least the date of service of this Complaint. Alkem's actions render this an exceptional case under 35 U.S.C. § 285.

ANSWER: Paragraph 53 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem states that, as required under Section 505(j)(2)(A)(vii), Alkem included a certification to each patent listed in the Orange Book in connection with the Reference Listed Drug, VELTASSA®, NDA No. 205739, at the time of its ANDA submission. Alkem further admits that Alkem's ANDA contains a certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the FDCA seeking approval for patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g, prior to the expiration of the '824 patent, which patent was listed in the Orange Book at the time of that ANDA submission. Alkem denies all remaining allegations of Paragraph 53.

54. Upon information and belief, Alkem has knowledge that if it were to receive approval from the FDA to market the Alkem Proposed ANDA Product and made that product available for sale and/or use by others, *e.g.*, by doctors, pharmacists, healthcare providers and patients, during the proposed shelf life of the products before expiration of the '824 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. Upon information and belief, Alkem has knowledge of such infringing use and also knows that the Alkem Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '824 patent.

ANSWER: Denied.

55. Upon information and belief, Alkem was aware of the '824 patent prior to filing the Alkem ANDA, including its Paragraph IV Certification allegations with respect to those patents. Upon information and belief, the proposed label for the Alkem Proposed ANDA Product induces others, e.g., doctors, pharmacists, healthcare providers and patients, to infringe the '824 patent, and based on Alkem's Paragraph IV Certification allegations, Alkem possesses the specific intent to encourage others to infringe.

ANSWER: Paragraph 55 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem states that, as required under Section 505(j)(2)(A)(vii),

Alkem included a certification to each patent listed in the Orange Book in connection with the Reference Listed Drug, VELTASSA®, NDA No. 205739, at the time of its ANDA submission. Alkem further admits that Alkem's ANDA contains a certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the FDCA seeking approval for patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g, prior to the expiration of the '824 patent, which patent was listed in the Orange Book at the time of that ANDA submission. Alkem denies all remaining allegations of Paragraph 55.

56. Plaintiffs will be irreparably harmed if Alkem is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '824 patent. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT III: THE '476 PATENT BY ALKEM

57. Plaintiffs repeat and reallege paragraphs 1-56 above as if fully set forth herein.

ANSWER: Alkem restates and incorporates by reference each of its answers in Paragraphs 1-56, as if fully set forth herein.

58. By filing the Alkem ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Alkem Proposed ANDA Product before the expiration of the '476 patent, Alkem committed an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

59. Moreover, if Alkem commercially makes, uses, offers to sell, or sells the Alkem Proposed ANDA Product within the United States, or imports the Alkem Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '476 patent, Alkem will further infringe the '476 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

60. Upon information and belief, the Alkem Proposed ANDA Product includes the active ingredient patiromer sorbitex calcium, claims bioequivalence to VELTASSA®, and has a proposed package insert that is substantially identical to VELTASSA®. Accordingly, using the Alkem Proposed ANDA Product in accordance with its label infringes at least claim 1 of the '476 patent.

ANSWER: Paragraph 60 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that Alkem submitted an ANDA seeking approval for patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g. Alkem further admits it has otherwise satisfied all statutory and regulatory requirements relating to its ANDA submission, including to show that its generic drug is "bioequivalent" to the reference listed drug. Alkem denies all remaining allegations of Paragraph 60.

61. Alkem has infringed at least claim 1 of the '476 patent under 35 U.S.C. § 271(e)(2) and, upon approval of Alkem's Proposed ANDA Product, will further infringe at least that claim under 35 U.S.C. §§ 271(a), (b), and/or (c) because the Alkem Proposed ANDA Product and the methods of using the Alkem Proposed ANDA Product, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the proposed package insert will meet each and every claim element of at least claim 1 of the '476 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

62. Alkem has had knowledge of the '476 patent since at least the date Alkem submitted the Alkem ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2). Alkem has had knowledge of the '476 patent by at least the date of service of this Complaint. Alkem's actions render this an exceptional case under 35 U.S.C. § 285.

ANSWER: Paragraph 62 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem states that, as required under Section 505(j)(2)(A)(vii), Alkem included a certification to each patent listed in the Orange Book in connection with the Reference Listed Drug, VELTASSA®, NDA No. 205739, at the time of its ANDA submission. Alkem further admits that Alkem's ANDA contains a certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the FDCA seeking approval for patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g, prior to the expiration of the '476 patent, which patent was listed in the Orange Book at the time of that ANDA submission. Alkem denies all remaining allegations of Paragraph 62.

63. Upon information and belief, Alkem has knowledge that if it were to receive approval from the FDA to market the Alkem Proposed ANDA Product and made that product

available for sale and/or use by others, *e.g.*, by doctors, pharmacists, healthcare providers and patients, during the proposed shelf life of the products before expiration of the '476 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. Upon information and belief, Alkem has knowledge of such infringing use and also knows that the Alkem Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '476 patent.

ANSWER: Denied.

64. Upon information and belief, Alkem was aware of the '476 patent prior to filing the Alkem ANDA, including its Paragraph IV Certification allegations with respect to those patents. Upon information and belief, the proposed label for the Alkem Proposed ANDA Product induces others, e.g., doctors, pharmacists, healthcare providers and patients, to infringe the '476 patent, and based on Alkem's Paragraph IV Certification allegations, Alkem possesses the specific intent to encourage others to infringe.

ANSWER: Paragraph 64 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem states that, as required under Section 505(j)(2)(A)(vii), Alkem included a certification to each patent listed in the Orange Book in connection with the Reference Listed Drug, VELTASSA®, NDA No. 205739, at the time of its ANDA submission. Alkem further admits that Alkem's ANDA contains a certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the FDCA seeking approval for patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g, prior to the expiration of the '476 patent, which patent was listed in the Orange Book at the time of that ANDA submission. Alkem denies all remaining allegations of Paragraph 64.

65. Plaintiffs will be irreparably harmed if Alkem is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '476 patent. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT IV:'212 PATENT BY ALKEM

66. Plaintiffs repeat and reallege paragraphs 1-65 above as if fully set forth herein.

ANSWER: Alkem restates and incorporates by reference each of its answers in Paragraphs 1-65, as if fully set forth herein.

67. By filing the Alkem ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Alkem Proposed ANDA Product before the expiration of the '212 patent, Alkem committed an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

68. Moreover, if Alkem commercially makes, uses, offers to sell, or sells the Alkem Proposed ANDA Product within the United States, or imports the Alkem Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '212 patent, Alkem will further infringe the '212 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

69. Upon information and belief, the Alkem Proposed ANDA Product includes the active ingredient patiromer sorbitex calcium, claims bioequivalence to VELTASSA®, and has a proposed package insert that is substantially identical to VELTASSA®. Accordingly, using the Alkem Proposed ANDA Product in accordance with its label infringes at least claim 1 of the '212 Patent.

ANSWER: Paragraph 69 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that Alkem submitted an ANDA seeking approval for patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g. Alkem further admits it has otherwise satisfied all statutory and regulatory requirements relating to its ANDA submission, including to show that its generic drug is "bioequivalent" to the reference listed drug. Alkem denies all remaining allegations of Paragraph 69.

70. Alkem has infringed at least claim 1 of the '212 patent under 35 U.S.C. § 271(e)(2) and, upon approval of Alkem's Proposed ANDA Product, will further infringe at least that claim under 35 U.S.C. §§ 271(a), (b), and/or (c) because the Alkem Proposed ANDA Product and the methods of using the Alkem Proposed ANDA Product, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the proposed package insert will meet each and every claim element of at least claim 1 of the '212 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

71. Alkem has had knowledge of the '212 patent since at least the date Alkem submitted the Alkem ANDA and was aware that submission of its ANDA constituted an act of

infringement under 35 U.S.C. § 271(e)(2). Alkem has had knowledge of the '212 patent by at least the date of service of this Complaint. Alkem's actions render this an exceptional case under 35 U.S.C. § 285.

ANSWER: Paragraph 71 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem states that, as required under Section 505(j)(2)(A)(vii), Alkem included a certification to each patent listed in the Orange Book in connection with the Reference Listed Drug, VELTASSA®, NDA No. 205739, at the time of its ANDA submission. Alkem further admits that Alkem's ANDA contains a certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the FDCA seeking approval for patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g, prior to the expiration of the '212 patent, which patent was listed in the Orange Book at the time of that ANDA submission. Alkem denies all remaining allegations of Paragraph 71.

72. Upon information and belief, Alkem has knowledge that if it were to receive approval from the FDA to market the Alkem Proposed ANDA Product and made that product available for sale and/or use by others, *e.g.*, by doctors, pharmacists, healthcare providers and patients, during the proposed shelf life of the products before expiration of the '212 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. Upon information and belief, Alkem has knowledge of such infringing use and also knows that the Alkem Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '212 patent.

ANSWER: Denied.

73. Upon information and belief, Alkem was aware of the '212 patent prior to filing the Alkem ANDA, including its Paragraph IV Certification allegations with respect to those patents. Upon information and belief, the proposed label for the Alkem Proposed ANDA Product induces others, *e.g.*, doctors, pharmacists, healthcare providers and patients, to infringe the '212 patent, and based on Alkem's Paragraph IV Certification allegations, Alkem possesses the specific intent to encourage others to infringe.

ANSWER: Paragraph 73 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem states that, as required under Section 505(j)(2)(A)(vii), Alkem included a certification to each patent listed in the Orange Book in connection with the

Reference Listed Drug, VELTASSA®, NDA No. 205739, at the time of its ANDA submission. Alkem further admits that Alkem's ANDA contains a certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the FDCA seeking approval for patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g, prior to the expiration of the '212 patent, which patent was listed in the Orange Book at the time of that ANDA submission. Alkem denies all remaining allegations of Paragraph 73.

74. Plaintiffs will be irreparably harmed if Alkem is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '212 patent. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT V: '363 PATENT BY ALKEM

75. Plaintiffs repeat and reallege paragraphs 1-74 above as if fully set forth herein.

ANSWER: Alkem restates and incorporates by reference each of its answers in Paragraphs 1-74, as if fully set forth herein.

76. By filing the Alkem ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Alkem Proposed ANDA Product before the expiration of the '363 patent, Alkem committed an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

77. Moreover, if Alkem commercially makes, uses, offers to sell, or sells the Alkem Proposed ANDA Product within the United States, or imports the Alkem Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '363 patent, Alkem will further infringe the '363 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

78. Upon information and belief, the Alkem Proposed ANDA Product includes the active ingredient patiromer sorbitex calcium and claims bioequivalence to VELTASSA®. Accordingly, the Alkem Proposed ANDA Product infringes at least claim 1 of the '363 patent.

ANSWER: Paragraph 78 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that Alkem submitted an ANDA seeking approval

for patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g. Alkem further admits it has otherwise satisfied all statutory and regulatory requirements relating to its ANDA submission, including to show that its generic drug is "bioequivalent" to the reference listed drug. Alkem denies all remaining allegations of Paragraph 78.

79. Alkem has infringed at least claim 1 of the '363 patent under 35 U.S.C. § 271(e)(2) and, upon approval of Alkem's Proposed ANDA Product, will further infringe at least that claim under 35 U.S.C. §§ 271(a), (b), and/or (c) because the Alkem Proposed ANDA Product and the methods of using the Alkem Proposed ANDA Product, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the proposed package insert will meet each and every claim element of at least claim 1 of the '363 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

80. Alkem has had knowledge of the '363 patent by at least the date of service of this Second Amended Complaint. Alkem's actions render this an exceptional case under 35 U.S.C. § 285.

ANSWER: Paragraph 80 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem states that, as required under Section 505(j)(2)(A)(vii), Alkem included a certification to each patent listed in the Orange Book in connection with the Reference Listed Drug, VELTASSA®, NDA No. 205739, at the time of its ANDA submission. Alkem further admits that Alkem's ANDA contains a certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the FDCA seeking approval for patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g, prior to the expiration of the '363 patent, which patent is listed in the Orange Book. Alkem denies all remaining allegations of Paragraph 80.

81. Upon information and belief, Alkem has knowledge that if it were to receive approval from the FDA to market the Alkem Proposed ANDA Product and made that product available for sale and/or use by others, *e.g.*, by doctors, pharmacists, healthcare providers and patients, during the proposed shelf life of the products before expiration of the '363 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. Upon information and belief, Alkem has knowledge of such infringing use and also knows that the Alkem Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '363 patent.

ANSWER: Denied.

82. Upon information and belief, the proposed label for the Alkem Proposed ANDA Product induces others, *e.g.*, doctors, pharmacists, healthcare providers and patients, to infringe the '363 patent, and Alkem possesses the specific intent to encourage others to infringe.

ANSWER: Paragraph 82 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem states that, as required under Section 505(j)(2)(A)(vii), Alkem included a certification to each patent listed in the Orange Book in connection with the Reference Listed Drug, VELTASSA®, NDA No. 205739, at the time of its ANDA submission. Alkem further admits that Alkem's ANDA contains a certification in accordance with Section 505(j)(2)(A)(vii)(IV) of the FDCA seeking approval for patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g, prior to the expiration of the '363 patent, which patent is listed in the Orange Book. Alkem denies all remaining allegations of Paragraph 82.

83. Plaintiffs will be irreparably harmed if Alkem is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '363 patent. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT VI: INFRINGEMENT OF THE '873 PATENT BY ASCENT

84. Plaintiffs repeat and reallege paragraphs 1-83 above as if fully set forth herein.

ANSWER: Alkem restates and incorporates by reference each of its answers in Paragraphs 1-83, as if fully set forth herein.

85. By filing the Ascent ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Ascent Proposed ANDA Product before the expiration of the '873 patent, Ascent committed an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER: The allegations of Paragraph 85 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information

sufficient to form a belief as to the truth of the allegations of Paragraph 85, and therefore denies all allegations of Paragraph 85.

86. Moreover, if Ascent commercially makes, uses, offers to sell, or sells the Ascent Proposed ANDA Product within the United States, or imports the Ascent Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '873 patent, Ascent will further infringe the '873 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: The allegations of Paragraph 86 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 86, and therefore denies all allegations of Paragraph 86.

87. Upon information and belief, the Ascent Proposed ANDA Product includes the active ingredient patiromer sorbitex calcium and claims bioequivalence to VELTASSA®. Accordingly, the Ascent Proposed ANDA Product infringes at least claim 1 of the '873 patent.

ANSWER: The allegations of Paragraph 87 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 87, and therefore denies all allegations of Paragraph 87.

88. Ascent has infringed at least claim 1 of the '873 patent under 35 U.S.C. § 271(e)(2) and, upon approval of Ascent's Proposed ANDA Product, will further infringe at least that claim under 35 U.S.C. §§ 271(a), (b), and/or (c) because the Ascent Proposed ANDA Product and the methods of using the Ascent Proposed ANDA Product, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the proposed package insert will meet each and every claim element of at least claim 1 of the '873 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations of Paragraph 88 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 88, and therefore denies all allegations of Paragraph 88.

89. Ascent has had knowledge of the '873 patent since at least the date Ascent submitted the Ascent ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2). Ascent has had knowledge of the '873 patent by at

least the date of service of this Complaint. Ascent's actions render this an exceptional case under 35 U.S.C. § 285.

ANSWER: The allegations of Paragraph 89 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 89, and therefore denies all allegations of Paragraph 89.

90. Upon information and belief, Ascent has knowledge that if it were to receive approval from the FDA to market the Ascent Proposed ANDA Product and made that product available for sale and/or use by others, *e.g.*, by doctors, pharmacists, healthcare providers and patients, during the proposed shelf life of the products before expiration of the '873 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. Upon information and belief, Ascent has knowledge of such infringing use and also knows that the Ascent Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '873 patent.

ANSWER: The allegations of Paragraph 90 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 90, and therefore denies all allegations of Paragraph 90.

91. Upon information and belief, Ascent was aware of the '873 patent prior to filing the Ascent ANDA, including its Paragraph IV Certification allegations with respect to those patents. Upon information and belief, the proposed label for the Ascent Proposed ANDA Product induces others, *e.g.*, doctors, pharmacists, healthcare providers and patients, to infringe the '873 patent, and based on Ascent's Paragraph IV Certification allegations, Ascent possesses the specific intent to encourage others to infringe.

ANSWER: The allegations of Paragraph 91 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 91, and therefore denies all allegations of Paragraph 91.

92. Plaintiffs will be irreparably harmed if Ascent is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '873 patent. Plaintiffs do not have an adequate remedy at law.

ANSWER: The allegations of Paragraph 92 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 92, and therefore denies all allegations of Paragraph 92.

COUNT VII: INFRINGEMENT OF THE '824 PATENT BY ASCENT

93. Plaintiffs repeat and reallege paragraphs 1-92 above as if fully set forth herein.

ANSWER: Alkem restates and incorporates by reference each of its answers in Paragraphs 1-92, as if fully set forth herein.

94. By filing the Ascent ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Ascent Proposed ANDA Product before the expiration of the '824 patent, Ascent committed an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER: The allegations of Paragraph 94 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 94, and therefore denies all allegations of Paragraph 94.

95. Moreover, if Ascent commercially makes, uses, offers to sell, or sells the Ascent Proposed ANDA Product within the United States, or imports the Ascent Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '824 patent, Ascent will further infringe the '824 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: The allegations of Paragraph 95 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 95, and therefore denies all allegations of Paragraph 95.

96. Upon information and belief, the Ascent Proposed ANDA Product includes the active ingredient patiromer sorbitex calcium and claims bioequivalence to VELTASSA®. Accordingly, the Ascent Proposed ANDA Product infringes at least claim 1 of the '824 patent.

ANSWER: The allegations of Paragraph 96 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 96, and therefore denies all allegations of Paragraph 96.

97. Ascent has infringed at least claim 1 of the '824 patent under 35 U.S.C. § 271(e)(2) and, upon approval of Ascent's Proposed ANDA Product, will further infringe at least that claim under 35 U.S.C. §§ 271(a), (b), and/or (c) because the Ascent Proposed ANDA Product and the methods of using the Ascent Proposed ANDA Product, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the proposed package insert will meet each and every claim element of at least claim 1 of the '824 patent , either literally or under the doctrine of equivalents.

ANSWER: The allegations of Paragraph 97 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 97, and therefore denies all allegations of Paragraph 97.

98. Ascent has had knowledge of the '824 patent since at least the date Ascent submitted the Ascent ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2). Ascent has had knowledge of the '824 patent by at least the date of service of this Complaint. Ascent's actions render this an exceptional case under 35 U.S.C. § 285.

ANSWER: The allegations of Paragraph 98 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 98, and therefore denies all allegations of Paragraph 98.

99. Upon information and belief, Ascent has knowledge that if it were to receive approval from the FDA to market the Ascent Proposed ANDA Product and made that product available for sale and/or use by others, *e.g.*, by doctors, pharmacists, healthcare providers and patients, during the proposed shelf life of the products before expiration of the '824 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. Upon information and belief, Ascent has knowledge of such infringing use and also knows that the Ascent Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '824 patent.

ANSWER: The allegations of Paragraph 99 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 99, and therefore denies all allegations of Paragraph 99.

100. Upon information and belief, Ascent was aware of the '824 patent prior to filing the Ascent ANDA, including its Paragraph IV Certification allegations with respect to those patents. Upon information and belief, the proposed label for the Ascent Proposed ANDA Product induces others, e.g., doctors, pharmacists, healthcare providers and patients, to infringe the '824 patent, and based on Ascent's Paragraph IV Certification allegations, Ascent possesses the specific intent to encourage others to infringe.

ANSWER: The allegations of Paragraph 100 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 100, and therefore denies all allegations of Paragraph 100.

101. Plaintiffs will be irreparably harmed if Ascent is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '824 patent. Plaintiffs do not have an adequate remedy at law.

ANSWER: The allegations of Paragraph 101 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 101, and therefore denies all allegations of Paragraph 101.

COUNT VIII: INFRINGEMENT OF THE '476 PATENT BY ASCENT

102. Plaintiffs repeat and reallege paragraphs 1-101 above as if fully set forth herein.

ANSWER: Alkem restates and incorporates by reference each of its answers in Paragraphs 1-101, as if fully set forth herein.

103. By filing the Ascent ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Ascent Proposed ANDA Product before the expiration of the '476 patent, Ascent committed an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER: The allegations of Paragraph 103 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 103, and therefore denies all allegations of Paragraph 103.

104. Moreover, if Ascent commercially makes, uses, offers to sell, or sells the Ascent Proposed ANDA Product within the United States, or imports the Ascent Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '476 patent, Ascent will further infringe the '476 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: The allegations of Paragraph 104 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 104, and therefore denies all allegations of Paragraph 104.

105. Upon information and belief, the Ascent Proposed ANDA Product includes the active ingredient patiromer sorbitex calcium, claims bioequivalence to VELTASSA®, and has a proposed package insert that is substantially identical to VELTASSA®. Accordingly, using the Ascent Proposed ANDA Product in accordance with its label infringes at least claim 1 of the '476 patent.

ANSWER: The allegations of Paragraph 105 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 105, and therefore denies all allegations of Paragraph 105.

106. Ascent has infringed at least claim 1 of the '476 patent under 35 U.S.C. § 271(e)(2) and, upon approval of Ascent's Proposed ANDA Product, will further infringe at least that claim under 35 U.S.C. §§ 271(a), (b), and/or (c) because the Ascent Proposed ANDA Product and the methods of using the Ascent Proposed ANDA Product, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the proposed package insert will meet each and every claim element of at least claim 1 of the '476 patent , either literally or under the doctrine of equivalents.

ANSWER: The allegations of Paragraph 106 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information

sufficient to form a belief as to the truth of the allegations of Paragraph 106, and therefore denies all allegations of Paragraph 106.

107. Ascent has had knowledge of the '476 patent since at least the date Ascent submitted the Ascent ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2). Ascent has had knowledge of the '476 patent by at least the date of service of this Complaint. Ascent's actions render this an exceptional case under 35 U.S.C. § 285.

ANSWER: The allegations of Paragraph 107 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 107, and therefore denies all allegations of Paragraph 107.

108. Upon information and belief, Ascent has knowledge that if it were to receive approval from the FDA to market the Ascent Proposed ANDA Product and made that product available for sale and/or use by others, *e.g.*, by doctors, pharmacists, healthcare providers and patients, during the proposed shelf life of the products before expiration of the '476 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. Upon information and belief, Ascent has knowledge of such infringing use and also knows that the Ascent Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '476 patent.

ANSWER: The allegations of Paragraph 108 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 108, and therefore denies all allegations of Paragraph 108.

109. Upon information and belief, Ascent was aware of the '476 patent prior to filing the Ascent ANDA, including its Paragraph IV Certification allegations with respect to those patents. Upon information and belief, the proposed label for the Ascent Proposed ANDA Product induces others, *e.g.*, doctors, pharmacists, healthcare providers and patients, to infringe the '476 patent, and based on Ascent's Paragraph IV Certification allegations, Ascent possesses the specific intent to encourage others to infringe.

ANSWER: The allegations of Paragraph 109 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information

sufficient to form a belief as to the truth of the allegations of Paragraph 109, and therefore denies all allegations of Paragraph 109.

110. Plaintiffs will be irreparably harmed if Ascent is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '476 patent. Plaintiffs do not have an adequate remedy at law.

ANSWER: The allegations of Paragraph 110 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 110, and therefore denies all allegations of Paragraph 110.

COUNT IX: INFRINGEMENT OF THE '212 PATENT BY ASCENT

111. Plaintiffs repeat and reallege paragraphs 1-110 above as if fully set forth herein.

ANSWER: Alkem restates and incorporates by reference each of its answers in Paragraphs 1-110, as if fully set forth herein.

112. By filing the Ascent ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Ascent Proposed ANDA Product before the expiration of the '212 patent, Ascent committed an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER: The allegations of Paragraph 112 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 112, and therefore denies all allegations of Paragraph 112.

113. Moreover, if Ascent commercially makes, uses, offers to sell, or sells the Ascent Proposed ANDA Product within the United States, or imports the Ascent Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '212 patent, Ascent will further infringe the '212 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: The allegations of Paragraph 113 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information

sufficient to form a belief as to the truth of the allegations of Paragraph 113, and therefore denies all allegations of Paragraph 113.

114. Upon information and belief, the Ascent Proposed ANDA Product includes the active ingredient patiromer sorbitex calcium, claims bioequivalence to VELTASSA®, and has a proposed package insert that is substantially identical to VELTASSA®. Accordingly, using the Ascent Proposed ANDA Product in accordance with its label infringes at least claim 1 of the '212 patent.

ANSWER: The allegations of Paragraph 114 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 114, and therefore denies all allegations of Paragraph 114.

115. Ascent has infringed at least claim 1 of the '212 patent under 35 U.S.C. § 271(e)(2) and, upon approval of Ascent's Proposed ANDA Product, will further infringe at least that claim under 35 U.S.C. §§ 271(a), (b), and/or (c) because the Ascent Proposed ANDA Product and the methods of using the Ascent Proposed ANDA Product, e.g., by doctors, pharmacists, healthcare providers and patients, according to the proposed package insert will meet each and every claim element of at least claim 1 of the '212 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations of Paragraph 115 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 115, and therefore denies all allegations of Paragraph 115.

116. Ascent has had knowledge of the '212 patent since at least the date Ascent submitted the Ascent ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2). Ascent has had knowledge of the '212 patent by at least the date of service of this Complaint. Ascent's actions render this an exceptional case under 35 U.S.C. § 285.

ANSWER: The allegations of Paragraph 116 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 116, and therefore denies all allegations of Paragraph 116.

117. Upon information and belief, Ascent has knowledge that if it were to receive approval from the FDA to market the Ascent Proposed ANDA Product and made that product available for sale and/or use by others, *e.g.*, by doctors, pharmacists, healthcare providers and patients, during the proposed shelf life of the products before expiration of the '212 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. Upon information and belief, Ascent has knowledge of such infringing use and also knows that the Ascent Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '212 patent.

ANSWER: The allegations of Paragraph 117 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 117, and therefore denies all allegations of Paragraph 117.

118. Upon information and belief, Ascent was aware of the '212 patent prior to filing the Ascent ANDA, including its Paragraph IV Certification allegations with respect to those patents. Upon information and belief, the proposed label for the Ascent Proposed ANDA Product induces others, *e.g.*, doctors, pharmacists, healthcare providers and patients, to infringe the '212 patent, and based on Ascent's Paragraph IV Certification allegations, Ascent possesses the specific intent to encourage others to infringe.

ANSWER: The allegations of Paragraph 118 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 118, and therefore denies all allegations of Paragraph 118.

119. Plaintiffs will be irreparably harmed if Ascent is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '212 patent. Plaintiffs do not have an adequate remedy at law.

ANSWER: The allegations of Paragraph 119 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 119, and therefore denies all allegations of Paragraph 119.

COUNT X: INFRINGEMENT OF THE '363 PATENT BY ASCENT

120. Plaintiffs repeat and reallege paragraphs 1-119 above as if fully set forth herein.

ANSWER: Alkem restates and incorporates by reference each of its answers in Paragraphs 1-119, as if fully set forth herein.

121. By filing the Ascent ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Ascent Proposed ANDA Product before the expiration of the '363 patent, Ascent committed an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER: The allegations of Paragraph 121 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 121, and therefore denies all allegations of Paragraph 121.

122. Moreover, if Ascent commercially makes, uses, offers to sell, or sells the Ascent Proposed ANDA Product within the United States, or imports the Ascent Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '363 patent, Ascent will further infringe the '363 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: The allegations of Paragraph 122 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 122, and therefore denies all allegations of Paragraph 122.

123. Upon information and belief, the Ascent Proposed ANDA Product includes the active ingredient patiromer sorbitex calcium and claims bioequivalence to VELTASSA®. Accordingly, the Ascent Proposed ANDA Product infringes at least claim 1 of the '363 patent.

ANSWER: The allegations of Paragraph 123 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 123, and therefore denies all allegations of Paragraph 123.

124. Ascent has infringed at least claim 1 of the '363 patent under 35 U.S.C. § 271(e)(2) and, upon approval of Ascent's Proposed ANDA Product, will further infringe at least that claim under 35 U.S.C. §§ 271(a), (b), and/or (c) because the Ascent Proposed ANDA Product and the methods of using the Ascent Proposed ANDA Product, *e.g.*, by doctors, pharmacists, healthcare providers and patients, according to the proposed package insert will meet each and every claim element of at least claim 1 of the '363 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations of Paragraph 124 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 124, and therefore denies all allegations of Paragraph 124.

125. Ascent has had knowledge of the '363 patent by at least the date of service of this Complaint. Ascent's actions render this an exceptional case under 35 U.S.C. § 285.

ANSWER: The allegations of Paragraph 125 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 125, and therefore denies all allegations of Paragraph 125.

126. Upon information and belief, Ascent has knowledge that if it were to receive approval from the FDA to market the Ascent Proposed ANDA Product and made that product available for sale and/or use by others, *e.g.*, by doctors, pharmacists, healthcare providers and patients, during the proposed shelf life of the products before expiration of the '363 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. Upon information and belief, Ascent has knowledge of such infringing use and also knows that the Ascent Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is especially made and/or adapted for use in the direct infringement of the '363 patent.

ANSWER: The allegations of Paragraph 126 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 126, and therefore denies all allegations of Paragraph 126.

127. Upon information and belief, the proposed label for the Ascent Proposed ANDA Product induces others, *e.g.*, doctors, pharmacists, healthcare providers and patients, to infringe the '363 patent, and Ascent possesses the specific intent to encourage others to infringe.

ANSWER: The allegations of Paragraph 127 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 127, and therefore denies all allegations of Paragraph 127.

128. Plaintiffs will be irreparably harmed if Ascent is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the '363 patent. Plaintiffs do not have an adequate remedy at law.

ANSWER: The allegations of Paragraph 128 are directed towards a Defendant other than Alkem. To the extent Alkem is required to answer, Alkem lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 128, and therefore denies all allegations of Paragraph 128.

DEFENSES

Without prejudice to each and every denial set forth above and without admitting any averments in the Complaint not otherwise admitted above, and without undertaking any of the burdens imposed by law on Plaintiffs Vifor Pharma, Inc. and Vifor (International) Ltd. (collectively, "Plaintiffs"), Alkem Laboratories Ltd. ("Alkem") avers and asserts the following defenses to the Complaint:

First Defense

The claims of United States Patent Nos. 8,147,873 ("the '873 patent"), 8,337,824 ("the '824 patent"), 9,492,476 ("the '476 patent"), 9,925,212 ("the '212 patent"), and 11,123,363 ("the '363 patent") are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including without limitation §§ 101, 102, 103 and/or 112, and/or any judicially-created basis for invalidation or unenforceability.

Second Defense

The manufacture, use, sale, offer for sale and/or importation of the proposed patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g, that are the subject of Alkem's Abbreviated New Drug Application No. 214075, does not and would not infringe, either directly or indirectly, any valid and/or enforceable claim of the '873, '824, '476, '212, or '363 patents, either literally or under the doctrine of equivalents.

Third Defense

Alkem has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '873, '824, '476, '212, or '363 patent.

Fourth Defense

The Court lacks subject matter jurisdiction over this action, including for any and all claims asserted under 35 U.S.C. § 271 (a), (b) or (c).

Fifth Defense

Alkem is exempt from liability under the safe harbor provision of 35 U.S.C. § 271(e)(1).

Sixth Defense

The Complaint fails to state a claim for exceptional case or willful infringement.

Seventh Defense

The Complaint fails to state a claim upon which relief can be granted.

Eighth Defense

Any additional defenses or counterclaims that discovery may reveal, including unenforceability.

Ninth Defense

Any defense asserted in any other action in which the '873, '824, '476, '212, or '363 patents are asserted.

COUNTERCLAIMS

Defendant/Counterclaim-Plaintiff Alkem Laboratories Ltd. ("Alkem"), for its Counterclaims against Plaintiffs/Counterclaim-Defendants Vifor Pharma, Inc. and Vifor (International) Ltd. (collectively, "Plaintiffs/Counterclaim-Defendants"), alleges as follows.

The Parties

1. Alkem is corporation operating and existing under the laws of India, having its head office at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, 400 013, India.

2. On information and belief and according to the Second Amended Complaint (D.I. 128, Compl. ¶ 2), Vifor Pharma, Inc. ("Vifor Pharma") is a corporation organized and existing under the laws of Delaware, with its principal place of business at 100 Cardinal Way, Redwood City, California 94063.

3. On information and belief and according to the Complaint (D.I. 1, Compl. ¶ 3), Vifor (International) Ltd. ("Vifor Ltd.") is a limited company organized and existing under the laws of Switzerland, with its principal place of business at Rechenstraße 37, St. Gallen, 9000, Switzerland.

Jurisdiction and Venue

4. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

5. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

6. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because they have availed themselves of the rights and privileges, and subjected themselves to the jurisdiction, of this forum by suing Alkem in this District, and, on information and belief, because Plaintiffs/Counterclaim-Defendants conduct substantial business in, and have regular systemic contact with, this District.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400(b).

Background

I. FDA Approval of New Brand-Name Drugs.

8. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman"), and as further amended by Title XI of the MMA, sets forth the rules that the U.S. Food and Drug Administration ("FDA") follows when considering whether to approve both brand-name and generic drugs.

9. Under the FFDCA, as amended by Hatch-Waxman and the MMA, an applicant seeking to market a new brand-name drug that has not been previously approved must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355.

10. An NDA includes, among other things, the number of any patent that the NDA holder asserts claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably by asserted against an

unauthorized party. 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2). The decision to submit patent infringement to the FDA rests solely with the NDA holder.

11. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

II. Generic Competition – Abbreviated New Drug Applications.

12. In 1984, Congress enacted the Hatch-Waxman Amendments to the FFDCA. Congress passed Hatch-Waxman, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition. Under Hatch-Waxman, a generic manufacturer submits what is called an Abbreviated New Drug Application ("ANDA").

13. To receive approval of its ANDA, an applicant must, *inter alia*, show that its generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355(j)(4)(F).

14. When filing an ANDA seeking approval for a generic version of a drug listed in the Orange Book, the ANDA generally must also "certify" that any patent information listed in the Orange Book does not preclude FDA approval of a generic version of the drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

15. An ANDA applicant may, *inter alia*, submit a so-called "paragraph III" certification stating that the applicant will not enter the market until the listed patents expire. *See* 21 U.S.C. § 355(j)(A)(vii)(III). Alternatively, when seeking FDA approval to market a drug product prior to patent expiration, an ANDA applicant generally submits a so-called "paragraph IV" certification asserting that the listed patent is invalid, unenforceable and/or will not be infringed. *See* 21 U.S.C. § 355(j)(A)(vii)(IV).

16. An applicant submitting an ANDA containing a paragraph IV certification must notify both the purported patent holder and NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B).

III. Patents-in-Suit.

17. On or about April 3, 2012, according to the electronic records of the United States Patent and Trademark Office ("USPTO"), United States Patent No. 8,147,873 ("the '873 patent"), titled "METHODS AND COMPOSITIONS FOR TREATMENT OF ION IMBALANCES," issued, on its face, to purported inventors Dominique Charmot and Mingjun Liu.

18. On or about December 25, 2012, according to the electronic records of the USPTO, United States Patent No. 8,337,824 ("the '824 patent"), titled "LINEAR POLYOL STABILIZED POLYFLUOROACRYLATE COMPOSITIONS," issued, on its face, to purported inventors Detlef Albrecht, Michael Burdick, Han-Ting Chang, Dominique Charmot, Ramakrishnan Chidambaram, Eric Connor, Sherin Halfon, I-Zu Huang, Mingjun Liu, Jonathan Mills, and Werner Strüver.

19. On or about November 15, 2016, according to the electronic records of the USPTO, United States Patent No. 9,492,476 ("the '476 patent"), titled "POTASSIUM-BINDING AGENTS FOR TREATING HYPERTENSION AND HYPERKALEMIA," issued, on its face, to purported inventors Gerrit Klaerner and Lance Berman.

20. On or about March 27, 2018, according to the electronic records of the USPTO, United States Patent No. 9,925,212 ("the '212 patent"), titled "POTASSIUM-BINDING AGENTS FOR TREATING HYPERTENSION AND HYPERKALEMIA," issued, on its face, to purported inventors Gerrit Klaerner and Lance Berman.

21. On or about September 21, 2021, according to the electronic records of the USPTO, United States Patent No. 11,123,363 ("the '363 patent"), titled "POTASSIUM-BINDING AGENTS FOR TREATING HYPERTENSION AND HYPERKALEMIA," issued, on its face, to purported inventors Gerrit Klaerner and Lance Berman

22. On information and belief, according to the electronic assignment records of the USPTO, Vifor Ltd. purports to be the assignee of '873, '824, '476, '212, and '363 patents.

23. On information and belief, one or more of Plaintiffs/Counterclaim-Defendants submitted, *inter alia*, the '873, '824, '476, '212, and '363 patents for listing in the Orange Book in connection with NDA No. 205739 for VELTASSA® (PATIROMER SORBITEX CALCIUM) 8.4 g; 16.8 g; 25.2 g.

24. On or about January 23, 2020, Vifor Pharma (f/k/a Relypsa, Inc.) and Vifor Ltd. sued Alkem in this District alleging infringement of, *inter alia*, the '873, '824, '476, and '212 patents.

25. On or about November 24, 2021, Vifor Pharma and Vifor Ltd. filed a Second Amended Complaint (D.I. 128) to allege infringement of, *inter alia*, the '363 patent.

IV. Alkem's Patiromer Powder for Oral Suspension, 8.4 g, 16.8 g, and 25.2 g.

26. Alkem filed an ANDA with the FDA seeking approval for patiromer powder for oral suspension, 8.4 g, 16.8 g, and 25.2 g ("Alkem's ANDA Products").

27. The FDA assigned Alkem's ANDA No. 214075.

28. Because Alkem seeks approval to market its ANDA Product prior to the expiration of the Orange Book-listed '873, '824, '476, '212, and '363 patents, Alkem's ANDA includes a "Paragraph IV Certification" to the '873, '824, '476, '212, and '363 patents in its ANDA.

29. Alkem provided proper and timely notice of its "Paragraph IV Certification" to the purported patent holder(s) and NDA holder(s) of record at that time, as required by 21 U.S.C. § 355(j)(2)(B), by Notifications dated December 19, 2019 (the "Dec. 2019 Notice Letter") and November 26, 2021 ("the Nov. 2021 Notice Letter"), together with an offer of confidential access to Alkem's ANDA.

30. The manufacture, use, sale, offer for sale or importation of Alkem's ANDA Product does not and will not infringe any valid and/or enforceable claim of the '873, '824, '476, '212, and '363 patents.

COUNT I
(Declaratory Judgment of Non-Infringement of the '873 Patent)

31. Alkem re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

32. There is an actual, substantial and continuing justiciable case or controversy between Alkem and Plaintiffs/Counterclaim-Defendants regarding whether the manufacture, use, offer for sale, sale or importation of Alkem's ANDA Product would infringe any valid and/or enforceable claim of the '873 patent.

33. Alkem's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '873 patent for at least the reasons set forth in Count II below and the Dec. 2019 Notice Letter, including because the claims of the '873 patent are invalid and/or unenforceable, *see Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1335 (Fed. Cir. 1998) (citing *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313 (1971) for proposition that "invalidity operates as a complete defense to infringement for any product, forever"). Additionally, Alkem's ANDA Product does not meet, *inter alia*, the

"pharmaceutical composition . . . suitable for intestinal administration" limitations of certain claims of the '873 patent.

34. Alkem is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Alkem's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '873 patent.

COUNT II
(Declaratory Judgment of Invalidity of the '873 Patent)

35. Alkem re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

36. There is an actual, substantial and continuing justiciable case or controversy between Alkem and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the '873 patent.

37. One or more claims of the '873 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, and/or under a judicially-created basis for invalidation or unenforceability.

38. For example, and not by way of limitation, one or more claims of the '873 patent are invalid under 35 U.S.C. §§ 102 and/or 103 because a person of ordinary skill in the art as to the '873 patent would have been motivated, and would have had a reasonable expectation of success, to prepare the alleged invention disclosed in the claims of the '873 patent, including in view of at least (but not necessarily limited to) the following: U.S. Patent No. 6,383,500 B1; International Publication No. WO 94/27619; Kionex Prescribing Information, PHYSICIANS' DESK REFERENCE 2608 (56th ed. 2002); U.S. Patent No. 4,837,015; Ho-Jung Kim & Sang-Woong Han,

Therapeutic Approach to Hyperkalemia, 92 NEPHRON 33 (Supp. I 2002); and SEYHAN N. EĞE, ORGANIC CHEMISTRY: STRUCTURE AND REACTIVITY (3d ed. 1994).

39. There is no objective evidence of non-obviousness of the claims of the '873 patent; nor would any evidence, should it exist, have the required nexus to the alleged invention of the '873 patent or outweigh the evidence in support of obviousness.

40. For example, and not by way of limitation, one or more claims of the '873 patent are also invalid under 35 U.S.C. § 112 for (1) failing to comply with the "written description" requirement; and/or (2) failing to comply with the "enablement" requirement. The '873 patent claims do not satisfy the written description requirement at least because the specification fails to describe what is claimed with sufficient detail such that those of ordinary skill in the art as relevant to the '873 patent can conclude that the inventors were in possession of the claimed invention as of the filing date. The '873 patent claims fail to satisfy the enablement requirement at least because the specification does not teach those of ordinary skill in the art as relevant to the '873 patent how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter.

41. Alkem is entitled to a judicial declaration that the claims of the '873 patent are invalid.

COUNT III
(Declaratory Judgment of Non-Infringement of the '824 Patent)

42. Alkem re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

43. There is an actual, substantial and continuing justiciable case or controversy between Alkem and Plaintiffs/Counterclaim-Defendants regarding whether the manufacture, use,

offer for sale, sale or importation of Alkem's ANDA Product would infringe any valid and/or enforceable claim of the '824 patent.

44. Alkem's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '824 patent for at least the reasons set forth in Count IV below and the Dec. 2019 Notice Letter, including because the claims of the '824 patent are invalid and/or unenforceable, *see Weatherchem*, 163 F.3d at 1335 (citing *Blonder-Tongue*, 402 U.S. 313, for proposition that "invalidity operates as a complete defense to infringement for any product, forever"). Additionally, Alkem will not directly practice the methods of certain claims of the '824 patent.

45. Alkem is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Alkem's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '824 patent.

COUNT IV
(Declaratory Judgment of Invalidity of the '824 Patent)

46. Alkem re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

47. There is an actual, substantial and continuing justiciable case or controversy between Alkem and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the '824 patent.

48. One or more claims of the '824 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, and/or under a judicially-created basis for invalidation or unenforceability.

49. For example, and not by way of limitation, one or more claims of the '824 patent are invalid under 35 U.S.C. §§ 102 and/or 103 because a person of ordinary skill in the art as to the '824 patent would have been motivated, and would have had a reasonable expectation of success, to prepare the alleged invention disclosed in the claims of the '824 patent, including in view of at least (but not necessarily limited to) the following: U.S. Patent No. 6,383,500 B1; International Publication No. WO 94/27619; Kionex Prescribing Information, PHYSICIANS' DESK REFERENCE 2608 (56th ed. 2002); U.S. Patent No. 4,837,015; Ho-Jung Kim & Sang-Woong Han, *Therapeutic Approach to Hyperkalemia*, 92 NEPHRON 33 (Supp. I 2002); SEYHAN N. EĞE, ORGANIC CHEMISTRY: STRUCTURE AND REACTIVITY (3d ed. 1994); U.S. Patent Application Publication No. 2005/0220752 A1; International Publication No. WO 2007/038801 A2; Veronica Wilbur & Tim Briscoe, *Constipation, Diarrhea and Irritable Bowel Syndrome*, *in* PHARMACOTHERAPEUTICS FOR ADVANCED PRACTICE: A PRACTICAL APPROACH 386 (2d ed. 2006); FLUIDS & ELECTROLYTES (Lippincott Williams & Wilkins 2007); HANDBOOK OF PHARMACEUTICAL EXCIPIENTS (5th ed. 2006); Manish M. Sood *et al*., *Emergency Management and Commonly Encountered Outpatient Scenarios in Patients with Hyperkalemia*, 82 MAYO CLINIC PROCEEDINGS 1553 (2007); Michael Emmett *et al*., *Effect of Three Laxatives and a Cation Exchange Resin on Fecal Sodium and Potassium Excretion*, 108 GASTROENTEROLOGY 752 (1995); U.S. Patent No. 5,188,825; and U.S. Patent Application Publication No. 2007/0092553 A1; Tsutomu Arakawa & Serge N. Timasheff, *Stabilization of Protein Structure by Sugars*, 21 BIOCHEMISTRY 6536 (1982); THE BIOMEDICAL ENGINEERING HANDBOOK VOL. II (Joseph D. Bronzino ed., 2d ed. 2000); EXCIPIENT DEVELOPMENT FOR PHARMACEUTICAL, BIOTECHNOLOGY, AND DRUG DELIVERY SYSTEMS (Ashok Katdare & Mahesh V. Chaubal eds., 2006); T.S. Ma, *Determination of Fluorine in Quantitative Organic Microanalysis*, 30 ANALYTICAL CHEMISTRY

1557 (1958); and Igor Makarovsky *et al*., *Toxic Chemical Compounds: Hydrogen Fluoride – The Protoplasmic Poison*, 10 ISR. MED. ASS'N J. 381 (2008).

50. There is no objective evidence of non-obviousness of the claims of the '824 patent; nor would any evidence, should it exist, have the required nexus to the alleged invention of the '824 patent or outweigh the evidence in support of obviousness.

51. For example, and not by way of limitation, one or more claims of the '824 patent are also invalid under 35 U.S.C. § 112 for (1) failing to comply with the "written description" requirement; (2) failing to comply with the "enablement" requirement; and/or (3) failing to comply with the "definiteness" requirement. The '824 patent claims do not satisfy the written description requirement at least because the specification fails to describe what is claimed with sufficient detail such that those of ordinary skill in the art as relevant to the '824 patent can conclude that the inventors were in possession of the claimed invention as of the filing date. The '824 patent claims fail to satisfy the enablement requirement at least because the specification does not teach those of ordinary skill in the art as relevant to the '824 patent how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. The '824 patent claims do not satisfy the definiteness requirement at least because those of ordinary skill in the art as relevant to the '824 patent would not understand the full scope of the '824 patent claims when read in light of the specification.

52. Alkem is entitled to a judicial declaration that the claims of the '824 patent are invalid.

COUNT V
(Declaratory Judgment of Non-Infringement of the '476 Patent)

53. Alkem re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

54. There is an actual, substantial and continuing justiciable case or controversy between Alkem and Plaintiffs/Counterclaim-Defendants regarding whether the manufacture, use, offer for sale, sale or importation of Alkem's ANDA Product would infringe any valid and/or enforceable claim of the '476 patent.

55. Alkem's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '476 patent for at least the reasons set forth in Count VI below and the Dec. 2019 Notice Letter, including because the claims of the '476 patent are invalid and/or unenforceable, *see Weatherchem*, 163 F.3d at 1335 (citing *Blonder-Tongue*, 402 U.S. 313, for proposition that "invalidity operates as a complete defense to infringement for any product, forever"). Additionally, Alkem will not directly practice the methods of certain claims of the '476 patent. Also, Alkem's ANDA Products do not comprise a "zeolite," a "zirconium silicate," a "molecular sieve," and/or a "zirconium germanate" as required by certain claims of the '476 patent.

56. Alkem is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Alkem's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '476 patent.

COUNT VI
(Declaratory Judgment of Invalidity of the '476 Patent)

57. Alkem re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

58. There is an actual, substantial and continuing justiciable case or controversy between Alkem and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the '476 patent.

59. One or more claims of the '476 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

60. For example, and not by way of limitation, one or more claims of the '476 patent are invalid under 35 U.S.C. §§ 102 and/or 103 because a person of ordinary skill in the art as to the '476 patent would have been motivated, and would have had a reasonable expectation of success, to prepare the alleged invention disclosed in the claims of the '476 patent, including in view of at least (but not necessarily limited to) the following: U.S. Patent No. 6,383,500 B1; International Publication No. WO 94/27619; Kionex Prescribing Information, PHYSICIANS' DESK REFERENCE 2608 (56th ed. 2002); U.S. Patent No. 4,837,015; Ho-Jung Kim & Sang-Woong Han, *Therapeutic Approach to Hyperkalemia*, 92 NEPHRON 33 (Supp. I 2002); SEYHAN N. EĞE, ORGANIC CHEMISTRY: STRUCTURE AND REACTIVITY (3d ed. 1994); U.S. Patent Application Publication No. 2005/0220752 A1; International Publication No. WO 2007/038801 A2; Gil Chernin et al., *Secondary Prevention of Hyperkalemia with Sodium Polystyrene Sulfonate in Cardiac and Kidney Patients on Renin-Angiotensin-Aldosterone System Inhibition Therapy*, 35 CLINICAL CARDIOLOGY 32 (2012); Jerry M Buysse *et al*., *PEARL-HF: Prevention of Hyperkalemia in Patients with Heart Failure Using a Novel Polymeric Potassium Binder, RLY5016*, 8 FUTURE CARDIOLOGY 17 (2012); U.S. Patent Application Publication No. 2009/0155370 A1; Thep Himathongkam *et al*., *Potassium-Aldosterone-Renin Interrelationships*, 41 J. CLINICAL

ENDOCRINOLOGY & METABOLISM 153 (1975); U.S. Patent Application Publication No. 2004/0105895 A1; U.S. Patent Application Publication No. 2011/0123604 A1; International Publication No. WO 2012/097017 A1; and U.S. Patent Application Publication No. 2012/0213847 A1; Ming-Fang Hsieh *et al*., *Higher Serum Potassium Level Associated with Late Stage Chronic Kidney Disease*, 34 CHANG GUNG MED. J. 418 (2011); Michiro Wakabayashi et al., *Study on the Dose-Response of a Jelly Preparation of Polystyrene Sulfonate Calcium in Hyperkalemia*, 26 THERAPEUTIC RES. 1727 (2005); Toshinao Tsuge *et al*., *Dose-Response of a Jelly Preparation of Calcium Polystyrene Sulfonate in Patients with Hyperkalemia (2nd Report): Changes in the Serum Potassium Level with or Without RAS Inhibitor*, 27 THERAPEUTIC RES. 2017 (2006); Lisa M. Einhorn *et al*., *The Frequency of Hyperkalemia and Its Significance in Chronic Kidney Disease*, 169 ARCHIVES INTERNAL MED. 1156 (2009); and Y. Tomino *et al*., *Dose-Response to a Jelly Preparation of Calcium Polystyrene Sulfonate in Patients with Hyperkalemia – Changes in Serum Potassium Levels with or Without a RAAS Inhibitor*, 68 CLINICAL NEPHROLOGY 379 (2007).

61. There is no objective evidence of non-obviousness of the claims of the '476 patent; nor would any evidence, should it exist, have the required nexus to the alleged invention of the '476 patent or outweigh the evidence in support of obviousness.

62. For example, and not by way of limitation, one or more claims of the '476 patent are also invalid under 35 U.S.C. § 112 for (1) failing to comply with the "written description" requirement; and/or (2) failing to comply with the "enablement" requirement. The '476 patent claims do not satisfy the written description requirement at least because the specification fails to describe what is claimed with sufficient detail such that those of ordinary skill in the art as relevant to the '476 patent can conclude that the inventors were in possession of the claimed invention as of the filing date. The '476 patent claims fail to satisfy the enablement requirement at least because

the specification does not teach those of ordinary skill in the art as relevant to the '476 patent how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter.

63. Alkem is entitled to a judicial declaration that the claims of the '476 patent are invalid.

COUNT VII
(Declaratory Judgment of Non-Infringement of the '212 Patent)

64. Alkem re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

65. There is an actual, substantial and continuing justiciable case or controversy between Alkem and Plaintiffs/Counterclaim-Defendants regarding whether the manufacture, use, offer for sale, sale or importation of Alkem's ANDA Product would infringe any valid and/or enforceable claim of the '212 patent.

66. Alkem's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '212 patent for at least the reasons set forth in Count VIII below and the Dec. 2019 Notice Letter, including because the claims of the '212 patent are invalid and/or unenforceable, *see Weatherchem Corp.*, 163 F.3d at 1335 (citing *Blonder-Tongue*, 402 U.S. 313, for proposition that "invalidity operates as a complete defense to infringement for any product, forever"). Additionally, Alkem will not directly practice the methods of certain claims of the '212 patent. Also, Alkem's ANDA Products do not comprise a "zeolite," a "zirconium silicate," a "molecular sieve", and/or a "zirconium germanate" as required by certain claims of the '212 patent.

67. Alkem is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Alkem's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '212 patent.

COUNT VIII
(Declaratory Judgment of Invalidity of the '212 Patent)

68. Alkem re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

69. There is an actual, substantial and continuing justiciable case or controversy between Alkem and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the '212 patent.

70. One or more claims of the '212 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, and/or under a judicially-created basis for invalidation or unenforceability.

71. For example, and not by way of limitation, one or more claims of the '212 patent are invalid under 35 U.S.C. §§ 102 and/or 103 because a person of ordinary skill in the art as to the '212 patent would have been motivated, and would have had a reasonable expectation of success, to prepare the alleged invention disclosed in the claims of the '212 patent, including in view of at least (but not necessarily limited to) the following: U.S. Patent No. 6,383,500 B1; International Publication No. WO 94/27619; Kionex Prescribing Information, PHYSICIANS' DESK REFERENCE 2608 (56th ed. 2002); U.S. Patent No. 4,837,015; Ho-Jung Kim & Sang-Woong Han, *Therapeutic Approach to Hyperkalemia*, 92 NEPHRON 33 (Supp. I 2002); SEYHAN N. EĞE, ORGANIC CHEMISTRY: STRUCTURE AND REACTIVITY (3d ed. 1994); U.S. Patent Application Publication No. 2005/0220752 A1; International Publication No. WO 2007/038801 A2; Gil

Chernin *et al*., *Secondary Prevention of Hyperkalemia with Sodium Polystyrene Sulfonate in Cardiac and Kidney Patients on Renin-Angiotensin-Aldosterone System Inhibition Therapy*, 35 CLINICAL CARDIOLOGY 32 (2012); Jerry M Buysse *et al*., *PEARL-HF: Prevention of Hyperkalemia in Patients with Heart Failure Using a Novel Polymeric Potassium Binder, RLY5016*, 8 FUTURE CARDIOLOGY 17 (2012); U.S. Patent Application Publication No. 2009/0155370 A1; Thep Himathongkam et al., *Potassium-Aldosterone-Renin Interrelationships*, 41 J. CLINICAL ENDOCRINOLOGY & METABOLISM 153 (1975); U.S. Patent Application Publication No. 2004/0105895 A1; U.S. Patent Application Publication No. 2011/0123604 A1; International Publication No. WO 2012/097017 A1; and U.S. Patent Application Publication No. 2012/0213847 A1; Ming-Fang Hsieh et al., *Higher Serum Potassium Level Associated with Late Stage Chronic Kidney Disease*, 34 CHANG GUNG MED. J. 418 (2011); Michiro Wakabayashi et al., *Study on the Dose-Response of a Jelly Preparation of Polystyrene Sulfonate Calcium in Hyperkalemia*, 26 THERAPEUTIC RES. 1727 (2005); Toshinao Tsuge *et al*., *Dose-Response of a Jelly Preparation of Calcium Polystyrene Sulfonate in Patients with Hyperkalemia (2nd Report): Changes in the Serum Potassium Level with or Without RAS Inhibitor*, 27 THERAPEUTIC RES. 2017 (2006); Lisa M. Einhorn *et al*., *The Frequency of Hyperkalemia and Its Significance in Chronic Kidney Disease*, 169 ARCHIVES INTERNAL MED. 1156 (2009); and Y. Tomino *et al*., *Dose-Response to a Jelly Preparation of Calcium Polystyrene Sulfonate in Patients with Hyperkalemia – Changes in Serum Potassium Levels with or Without a RAAS Inhibitor*, 68 CLINICAL NEPHROLOGY 379 (2007).

72. There is no objective evidence of non-obviousness of the claims of the ‘212 patent; nor would any evidence, should it exist, have the required nexus to the alleged invention of the ‘212 patent or outweigh the evidence in support of obviousness.

73. For example, and not by way of limitation, one or more claims of the '212 patent are also invalid under 35 U.S.C. § 112 for (1) failing to comply with the "written description" requirement; and/or (2) failing to comply with the "enablement" requirement. The '212 patent claims do not satisfy the written description requirement at least because the specification fails to describe what is claimed with sufficient detail such that those of ordinary skill in the art as relevant to the '212 patent can conclude that the inventors were in possession of the claimed invention as of the filing date. The '212 patent claims fail to satisfy the enablement requirement at least because the specification does not teach those of ordinary skill in the art as relevant to the '212 patent how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter.

74. Alkem is entitled to a judicial declaration that the claims of the '212 patent are invalid.

COUNT IX
(Declaratory Judgment of Non-Infringement of the '363 Patent)

75. Alkem re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

76. There is an actual, substantial and continuing justiciable case or controversy between Alkem and Plaintiffs/Counterclaim-Defendants regarding whether the manufacture, use, offer for sale, sale or importation of Alkem's ANDA Product would infringe any valid and/or enforceable claim of the '363 patent.

77. Alkem's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '363 patent for at least the reasons set forth in Count X below and the Nov. 2021 Notice Letter, including because the claims of the '363 patent are invalid and/or unenforceable, *see Weatherchem Corp.*, 163 F.3d at 1335 (citing *Blonder-*

Tongue, 402 U.S. 313, for proposition that "invalidity operates as a complete defense to infringement for any product, forever").

78. Alkem is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of Alkem's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '363 patent.

COUNT X
(Declaratory Judgment of Invalidity of the '363 Patent)

79. Alkem re-asserts and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

80. There is an actual, substantial and continuing justiciable case or controversy between Alkem and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the '363 patent.

81. One or more claims of the '363 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, and/or under a judicially-created basis for invalidation or unenforceability.

82. For example, and not by way of limitation, one or more claims of the '363 patent are invalid under 35 U.S.C. §§ 102 and/or 103 because a person of ordinary skill in the art as to the '363 patent would have been motivated, and would have had a reasonable expectation of success, to prepare the alleged invention disclosed in the claims of the '363 patent, including in view of at least (but not necessarily limited to) the following: U.S. Patent No. 6,383,500 B1; International Publication No. WO 94/27619; Kionex Prescribing Information, PHYSICIANS' DESK REFERENCE 2608 (56th ed. 2002); U.S. Patent No. 4,837,015; Ho-Jung Kim & Sang-Woong Han, *Therapeutic Approach to Hyperkalemia*, 92 NEPHRON 33 (Supp. I 2002); SEYHAN N. EĞE,

ORGANIC CHEMISTRY: STRUCTURE AND REACTIVITY (3d ed. 1994); U.S. Patent Application Publication No. 2005/0220752 A1; International Publication No. WO 2007/038801 A2; International Application Publication No. WO 2007/038802 A2; THE BIOMEDICAL ENGINEERING HANDBOOK VOL. II (Joseph D. Bronzino ed., 2d ed. 2000); Michael Emmett *et al*., *Effect of Three Laxatives and a Cation Exchange Resin on Fecal Sodium and Potassium Excretion*, 108 GASTROENTEROLOGY 752 (1995); Gil Chernin *et al*., *Secondary Prevention of Hyperkalemia with Sodium Polystyrene Sulfonate in Cardiac and Kidney Patients on Renin-Angiotensin-Aldosterone System Inhibition Therapy*, 35 CLINICAL CARDIOLOGY 32 (2012); Jerry M Buysse *et al*., *PEARL-HF: Prevention of Hyperkalemia in Patients with Heart Failure Using a Novel Polymeric Potassium Binder, RLY5016*, 8 FUTURE CARDIOLOGY 17 (2012); U.S. Patent Application Publication No. 2009/0155370 A1; Thep Himathongkam et al., *Potassium-Aldosterone-Renin Interrelationships*, 41 J. CLINICAL ENDOCRINOLOGY & METABOLISM 153 (1975); U.S. Patent Application Publication No. 2004/0105895 A1; U.S. Patent Application Publication No. 2011/0123604 A1; International Publication No. WO 2012/097017 A1; U.S. Patent Application Publication No. 2012/0213847 A1; Ming-Fang Hsieh et al., *Higher Serum Potassium Level Associated with Late Stage Chronic Kidney Disease*, 34 CHANG GUNG MED. J. 418 (2011); Michiro Wakabayashi et al., *Study on the Dose-Response of a Jelly Preparation of Polystyrene Sulfonate Calcium in Hyperkalemia*, 26 THERAPEUTIC RES. 1727 (2005); Toshinao Tsuge *et al*., *Dose-Response of a Jelly Preparation of Calcium Polystyrene Sulfonate in Patients with Hyperkalemia (2nd Report): Changes in the Serum Potassium Level with or Without RAS Inhibitor*, 27 THERAPEUTIC RES. 2017 (2006); Lisa M. Einhorn *et al*., *The Frequency of Hyperkalemia and Its Significance in Chronic Kidney Disease*, 169 ARCHIVES INTERNAL MED. 1156 (2009); Y. Tomino *et al*., *Dose-Response to a Jelly Preparation of Calcium Polystyrene Sulfonate in Patients with*

Hyperkalemia – Changes in Serum Potassium Levels with or Without a RAAS Inhibitor, 68 CLINICAL NEPHROLOGY 379 (2007); International Publication No. WO 2010/132662 A1; Bertram Pitt *et al.*, *Evaluation of the efficacy and safety of RLY5016, a polymeric potassium binder, in a double-blind, placebo-controlled study in patients with chronic heart failure (the PEARL-HF) trial*, 32 EUR. HEART J. 820 (2011); U.S. Patent Application Publication No. 2010/0111891 A1; and 7th Global CardioVascular Clinical Trialists Forum Final Program and Abstracts (Dec. 2010).

83. There is no objective evidence of non-obviousness of the claims of the '363 patent; nor would any evidence, should it exist, have the required nexus to the alleged invention of the '363 patent or outweigh the evidence in support of obviousness.

84. Alkem is entitled to a judicial declaration that the claims of the '363 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Alkem respectfully prays for judgment in its favor and against Plaintiffs/Counterclaim-Defendants:

(a). Declaring that the manufacture, use, offer for sale, sale and/or importation of Alkem's ANDA Products has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '873, '824, '476, '212, and '363 patents;

(b). Declaring that the claims of the '873, '824, '476, '212, and '363 patents are invalid;

(c). Ordering that Plaintiffs/Counterclaim-Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Alkem;

(d). Declaring this case exceptional and awarding Alkem its reasonable attorneys' fees and costs under 35 U.S.C. § 285; and,

(e). Awarding Alkem such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Alkem hereby demands a jury trial on all issues so triable.

HEYMAN ENERIO
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