IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RELYPSA, INC. AND VIFOR (INTERNATIONAL) LTD.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
ALKEM LABORATORIES LTD. and ASCENT PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Relypsa, Inc. ("Relypsa") and Vifor (International) Ltd. ("Vifor") (collectively, "Plaintiffs") hereby assert the following claims for patent infringement against Defendants Alkem Laboratories Ltd. ("Alkem") and Ascent Pharmaceuticals, Inc. ("Ascent"), and allege as follows:

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"), and 9,925,212 ("the '212 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.

THE PARTIES

2. Plaintiff Relypsa 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. Plaintiff Vifor 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.

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.

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.

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 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.

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 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.

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 is the assignee of the ’476 patent. A copy of the ’476 patent is attached hereto as Exhibit C.

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 is the assignee of the ’212 patent. A copy of the ’212 patent is attached hereto as Exhibit D.

THE VELTASSA® DRUG PRODUCT

10. Relypsa 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. Relypsa received approval for VELTASSA® from the FDA in October 2015.

11. 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®.

ACTS GIVING RISE TO THIS ACTION

12. 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.

13. 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.

14. On or about December 20, 2019, Plaintiffs received a letter dated December 19, 2019 from Alkem's counsel stating that the Alkem ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Alkem 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.

15. This action is being commenced before the expiration of 45 days from the date Plaintiffs received the Alkem Paragraph IV Certification Letter.

16. 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.

17. 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.

18. On or about December 10, 2019, Plaintiffs received a letter dated December 9, 2019 from Ascent's counsel stating that the Ascent ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Ascent Paragraph IV Certification"), 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.

19. This action is being commenced before the expiration of 45 days from the date Plaintiffs received the Ascent Paragraph IV Certification Letter.

JURISDICTION AND VENUE

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

21. 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, and '212 patents.

22. 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.

23. 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.

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

25. 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.).

26. 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.).

27. 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.

28. 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 21 above, and continuously transacts business in this Judicial District, as set forth in paragraphs 22–24 above.

29. 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 '824, '476, and '212 patents.

30. 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.

31. 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.

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

33. 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.

34. 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.).

35. 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.).

36. 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.

COUNT I: INFRINGEMENT OF THE '873 PATENT BY ALKEM

37. Plaintiffs repeat and reallege paragraphs 1-36 above as if fully set forth herein.

38. 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).

39. 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).

40. 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.

41. 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.

42. 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.

43. 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.

44. 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.

45. 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.

COUNT II: INFRINGEMENT OF THE ’824 PATENT BY ALKEM

46. Plaintiffs repeat and reallege paragraphs 1-45 above as if fully set forth herein.

47. 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).

48. 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).

49. 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.

50. 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.

51. 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.

52. 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.

53. 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.

54. 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.

COUNT III: INFRINGEMENT OF THE ’476 PATENT BY ALKEM

55. Plaintiffs repeat and reallege paragraphs 1-54 above as if fully set forth herein.

56. 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).

57. 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).

58. 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.

59. 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.

60. 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.

61. 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.

62. 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.

63. 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.

COUNT IV: INFRINGEMENT OF ’212 PATENT BY ALKEM

64. Plaintiffs repeat and reallege paragraphs 1-63 above as if fully set forth herein.

65. 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).

66. 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).

67. 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.

68. 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.

69. 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.

70. 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.

71. 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.

72. 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.

COUNT V: INFRINGEMENT OF THE ’824 PATENT BY ASCENT

73. Plaintiffs repeat and reallege paragraphs 1-72 above as if fully set forth herein.

74. 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).

75. 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).

76. 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.

77. 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.

78. 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.

79. 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.

80. 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.

81. 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.

COUNT VI: INFRINGEMENT OF THE ’476 PATENT BY ASCENT

82. Plaintiffs repeat and reallege paragraphs 1-81 above as if fully set forth herein.

83. 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).

84. 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).

85. 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.

86. 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.

87. 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.

88. 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.

89. 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.

90. 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.

COUNT VII: INFRINGEMENT OF THE ’212 PATENT BY ASCENT

91. Plaintiffs repeat and reallege paragraphs 1-90 above as if fully set forth herein.

92. 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).

93. 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).

94. 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.

95. 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.

96. 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.

97. 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.

98. 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.

99. 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Alkem has infringed one or more claims of the ’873 patent by filing the Alkem ANDA;

B. A Judgment that Alkem has infringed, and that Alkem’s making, using, offering to sell, selling, or importing the Alkem Proposed ANDA Product would constitute infringement of one or more claims of the ’873 patent, and/or induce or contribute to the infringement of one or more claims of the ’873 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

C. A permanent injunction restraining and enjoining Alkem, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Alkem Proposed ANDA Product until after the expiration of the ’873 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

D. An Order that the effective date of any approval of the Alkem ANDA relating to the Alkem Proposed ANDA Product be a date that is not earlier than the expiration date of the ’873 patent, as extended, plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

E. A Judgment that Alkem has infringed one or more claims of the ’824 patent by filing the Alkem ANDA;

F. A Judgment that Alkem has infringed, and that Alkem’s making, using, offering to sell, selling, or importing the Alkem Proposed ANDA Product would constitute infringement of one or more claims of the ’824 patent, and/or induce or contribute to the infringement of one or more claims of the ’824 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

G. A permanent injunction restraining and enjoining Alkem, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Alkem Proposed ANDA Product until after the expiration of the ’824 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

H. An Order that the effective date of any approval of the Alkem ANDA relating to the Alkem Proposed ANDA Product be a date that is not earlier than the expiration date of the ’824 patent, as extended, plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

I. A Judgment that Alkem has infringed one or more claims of the ’476 patent by filing the Alkem ANDA;

J. A Judgment that Alkem has infringed, and that Alkem’s making, using, offering to sell, selling, or importing the Alkem Proposed ANDA Product would constitute infringement

of one or more claims of the ’476 patent, and/or induce or contribute to the infringement of one or more claims of the ’476 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

K. A permanent injunction restraining and enjoining Alkem, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Alkem Proposed ANDA Product until after the expiration of the ’476 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

L. An Order that the effective date of any approval of the Alkem ANDA relating to the Alkem Proposed ANDA Product be a date that is not earlier than the expiration date of the ’476 patent, as extended, plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

M. A Judgment that Alkem has infringed one or more claims of the ’212 patent by filing the Alkem ANDA;

N. A Judgment that Alkem has infringed, and that Alkem’s making, using, offering to sell, selling, or importing the Alkem Proposed ANDA Product would constitute infringement of one or more claims of the ’212 patent, and/or induce or contribute to the infringement of one or more claims of the ’212 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

O. A permanent injunction restraining and enjoining Alkem, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Alkem Proposed ANDA Product until after the expiration of the ’212 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

P. An Order that the effective date of any approval of the Alkem ANDA relating to the Alkem Proposed ANDA Product be a date that is not earlier than the expiration date of the ’212 patent, as extended, plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

Q. A Judgment that Ascent has infringed one or more claims of the ’824 patent by filing the Ascent ANDA;

R. A Judgment that Ascent has infringed, and that Ascent’s making, using, offering to sell, selling, or importing the Ascent Proposed ANDA Product would constitute infringement of one or more claims of the ’824 patent, and/or induce or contribute to the infringement of one or more claims of the ’824 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

S. A permanent injunction restraining and enjoining Ascent, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Ascent Proposed ANDA Product until after the expiration of ’824 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

T. An Order that the effective date of any approval of the Ascent ANDA relating to the Ascent Proposed ANDA Product be a date that is not earlier than the expiration date of the ’824 patent, as extended, plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

U. A Judgment that Ascent has infringed one or more claims of the ’476 patent by filing the Ascent ANDA;

V. A Judgment that Ascent has infringed, and that Ascent’s making, using, offering to sell, selling, or importing the Ascent Proposed ANDA Product would constitute infringement

of one or more claims of the ’476 patent, and/or induce or contribute to the infringement of one or more claims of the ’476 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

W. A permanent injunction restraining and enjoining Ascent, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Ascent Proposed ANDA Product until after the expiration of ’476 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

X. An Order that the effective date of any approval of the Ascent ANDA relating to the Ascent Proposed ANDA Product be a date that is not earlier than the expiration date of the ’476 patent, as extended, plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

Y. A Judgment that Ascent has infringed one or more claims of the ’212 patent by filing the Ascent ANDA;

Z. A Judgment that Ascent has infringed, and that Ascent’s making, using, offering to sell, selling, or importing the Ascent Proposed ANDA Product would constitute infringement of one or more claims of the ’212 patent, and/or induce or contribute to the infringement of one or more claims of the ’212 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

AA. A permanent injunction restraining and enjoining Ascent, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Ascent Proposed ANDA Product until after the expiration of ’212 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

BB. An Order that the effective date of any approval of the Ascent ANDA relating to the Ascent Proposed ANDA Product be a date that is not earlier than the expiration date of the '212 patent, as extended, plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

CC. A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and an award of reasonable attorneys' fees, expenses, and disbursements of this action;

DD. An award of Plaintiffs' reasonable costs and expenses in this action; and

EE. Such other and further relief as the Court may deem just and proper.

Date: January 23, 2020

Respectfully submitted,

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