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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD. Plaintiff, v. ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC LIMITED, ALEMBIC GLOBAL HOLDING SA and ALEMBIC PHARMACEUTICALS INC., Defendants.	Civil Action No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants Alembic Pharmaceuticals Limited ("Alembic Pharmaceuticals Ltd."), Alembic Limited, Alembic Global Holding SA and Alembic Pharmaceuticals Inc. (collectively, "Alembic"), alleges as follows:

THE PARTIES

1. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

Otsuka is engaged in the research, development, manufacture and sale of pharmaceutical products.

2. Upon information and belief, Alembic Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Alembic Road, Vadodara 390003, Gujarat, India.

3. Upon information and belief, Alembic Limited is a corporation organized and existing under the laws of India, having its principal place of business at Alembic Road, Vadodara 390003, Gujarat, India. Upon information and belief, Alembic Pharmaceuticals Ltd. is a wholly-owned subsidiary of Alembic Limited.

4. Upon information and belief, Alembic Global Holding SA is a corporation organized and existing under the laws of Switzerland, having its principal place of business at 40, Rue Fritz-Courvoisier, 2300 La Chaux-de-Fonds, Switzerland. Upon information and belief, Alembic Global Holding SA is a wholly-owned subsidiary of Alembic Pharmaceuticals Ltd.

5. Upon information and belief, Alembic Pharmaceuticals Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 116 Village Blvd., Suite 200, Princeton, New Jersey 08650. Upon information and belief, Alembic Pharmaceuticals Inc. is a wholly-owned subsidiary of Alembic Global Holding SA.

NATURE OF THE ACTION

6. This is an action for infringement of U.S. Patent No. 8,017,615 ("the '615 patent"), U.S. Patent No. 8,580,796 ("the '796 patent"), U.S. Patent No. 8,642,760 ("the '760 patent") and U.S. Patent No. 8,518,421 ("the '421 patent"), arising under the United States patent laws, Title 35, United States Code, §100 *et seq*., including 35 U.S.C. §§ 271 and 281. This action relates to Alembic Pharmaceuticals Ltd.'s filing of Abbreviated New Drug Applications

("ANDAs") under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to manufacture, use, sale, offer to sell and import generic pharmaceutical products ("Alembic Pharmaceuticals Ltd.'s generic products") prior to the expirations of the asserted patents.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

8. Upon information and belief, this Court has jurisdiction over Alembic Pharmaceuticals Ltd. Alembic Pharmaceuticals Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Alembic Pharmaceuticals Ltd., directly or through its subsidiaries Alembic Global Holding SA and Alembic Pharmaceuticals Inc., manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Alembic Pharmaceuticals Ltd. purposefully has conducted and continues to conduct business, directly or through its subsidiaries Alembic Global Holding SA and Alembic Pharmaceuticals Inc., in this judicial district, and this judicial district is a likely destination of Alembic Pharmaceuticals Ltd.'s generic products.

9. Upon information and belief, this Court has jurisdiction over Alembic Limited. Upon information and belief, Alembic Limited, directly or through its subsidiaries Alembic Pharmaceuticals Ltd., Alembic Global Holding SA and Alembic Pharmaceuticals Inc., manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district.

10. Upon information and belief, this Court has jurisdiction over Alembic Global Holding SA. Upon information and belief, Alembic Global Holding SA, directly or through its

subsidiary Alembic Pharmaceuticals Inc., manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Alembic's website, http://alembicglobal.ch/index.html, states that "Alembic Global Holding SA is the headquarter for all the overseas business in countries like USA, Europe, UAE, Australia and other developed markets."

11. Upon information and belief, this Court has jurisdiction over Alembic Pharmaceuticals Inc. Upon information and belief, Alembic Pharmaceuticals Inc. has its principal place of business in New Jersey. Upon information and belief, Alembic Pharmaceuticals Inc., directly or indirectly, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Alembic's website, http://alembicglobal.ch/AlembicUSA.html, states that:

> Alembic Pharmaceuticals Inc is the 100 % subsidiary of the Alembic Global Holding SA. It is located in New Jersey, USA. The basic objective of forming a wholly owned overseas subsidiary in USA is to establish a globally recognized organization in USA. Alembic aims as [*sic*] creating a strong US presence Alembic has filed 57 ANDAs, received approval for 24 and has commercialized 15 of the approved filings. We has [*sic*] also initiated Para IV and NDA filings and strengthened our technology capability in new finished dosage forms.

12. Upon information and belief, Alembic Pharmaceuticals Ltd., Alembic Limited, Alembic Global Holding SA and Alembic Pharmaceuticals Inc. hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling and distributing generic products. Upon information and belief, Alembic Pharmaceuticals Ltd. and Alembic Limited are located at the same address. Upon information and belief, Chirayu R. Amin serves as Chairman of Alembic Pharmaceuticals Ltd., Alembic Limited and Alembic Global Holding SA.

13. Upon information and belief, Alembic Pharmaceuticals Ltd., Alembic Limited, Alembic Global Holding SA and Alembic Pharmaceuticals Inc. work in concert with each other

with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

14. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § l400(b).

FIRST COUNT FOR PATENT INFRINGEMENT

15. The U.S. Patent and Trademark Office ("PTO") issued the '615 patent on September 13, 2011, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '615 patent is attached as Exhibit A.

16. Otsuka is the owner of the '615 patent by virtue of assignment.

17. The '615 patent expires on December 16, 2024 (including pediatric exclusivity).

18. The '615 patent is directed to and claims, *inter alia,* pharmaceutical solid oral preparations and processes for preparing pharmaceutical solid oral preparations.

19. Otsuka is the holder of New Drug Application ("NDA") No. 21-436 for aripiprazole tablets, which the FDA approved on November 15, 2002.

20. Otsuka lists the '615 patent in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 21-436.

21. Otsuka markets aripiprazole tablets in the United States under the trademark Abilify®.

22. Upon information and belief, Alembic Pharmaceuticals Ltd. submitted ANDA No. 20-2101 to the FDA, under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to manufacture, use, sale, offer to sell and import generic products containing 2, 5, 10, 15, 20 and 30 mg of aripiprazole ("Alembic Pharmaceuticals Ltd.'s tablet generic products") in the United States.

23. Otsuka received a letter from Alembic Pharmaceuticals Ltd. dated March 27, 2014 ("Alembic Pharmaceuticals Ltd.'s letter"), purporting to include a Notice of Certification for ANDA No. 20-2101 under 21 U.S.C. § 355(j)(2)(B)(ii) and (iv) and 21 C.F.R. § 314.95(c)(6) as to the '615 patent.

24. Alembic Pharmaceuticals Ltd.'s letter alleges that the active ingredient in Alembic Pharmaceuticals Ltd.'s tablet generic products for which it seeks approval is aripiprazole.

25. Upon information and belief, Alembic Pharmaceuticals Ltd.'s tablet generic products will, if approved and marketed, infringe at least one claim of the '615 patent.

26. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Alembic Pharmaceuticals Ltd. has infringed at least one claim of the '615 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-2101 seeking approval to manufacture, use, sale, offer to sell and import Alembic Pharmaceuticals Ltd.'s tablet generic products before the expiration date of the '615 patent.

27. Upon information and belief, Alembic Pharmaceuticals Ltd.'s actions relating to Alembic Pharmaceuticals Ltd.'s ANDA No. 20-2101 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Alembic Limited, Alembic Global Holding SA and Alembic Pharmaceuticals Inc.

SECOND COUNT FOR PATENT INFRINGEMENT

28. Otsuka realleges, and incorporates in full herein, paragraphs 15-18.

29. Otsuka is the holder of NDA No. 21-729 for orally disintegrating tablets (ODT) containing aripiprazole, which the FDA approved on June 7, 2006.

30. Otsuka lists the '615 patent in the Orange Book for NDA No. 21-729.

31. Otsuka markets ODT containing aripiprazole in the United States under the trademark Abilify®.

32. Upon information and belief, Alembic Pharmaceuticals Ltd. submitted ANDA No. 20-2102 to the FDA, under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to manufacture, use, sale, offer to sell and import generic products containing 10 and 15 mg of aripiprazole ("Alembic Pharmaceuticals Ltd.'s ODT generic products") in the United States.

33. Alembic Pharmaceuticals Ltd.'s letter purports to include a Notice of Certification for ANDA No. 20-2102 under 21 U.S.C. § 355(j)(2)(B)(ii) and (iv) and 21 C.F.R. § 314.95(c)(6) as to the '615 patent.

34. Alembic Pharmaceuticals Ltd.'s letter alleges that the active ingredient in Alembic Pharmaceuticals Ltd.'s ODT generic products for which it seeks approval is aripiprazole.

35. Upon information and belief, Alembic Pharmaceuticals Ltd.'s ODT generic products will, if approved and marketed, infringe at least one claim of the '615 patent.

36. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Alembic Pharmaceuticals Ltd. has infringed at least one claim of the '615 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-2102 seeking approval to manufacture, use, sale, offer to sell and import Alembic Pharmaceuticals Ltd.'s ODT generic products before the expiration date of the '615 patent.

37. Upon information and belief, Alembic Pharmaceuticals Ltd.'s actions relating to Alembic Pharmaceuticals Ltd.'s ANDA No. 20-2102 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Alembic Limited, Alembic Global Holding SA and Alembic Pharmaceuticals Inc.

THIRD COUNT FOR PATENT INFRINGEMENT

38. Otsuka realleges, and incorporates in full herein, paragraphs 19, 21, 22 and 24.

39. The PTO issued the '796 patent on November 12, 2013, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '796 patent is attached as Exhibit B.

40. Otsuka is the owner of the '796 patent by virtue of assignment.

41. The '796 patent expires on March 25, 2023 (including pediatric exclusivity).

42. The '796 patent is directed to and claims, *inter alia*, aripiprazole crystals.

43. Otsuka lists the '796 patent in the Orange Book for NDA No. 21-436.

44. Alembic Pharmaceuticals Ltd.'s letter purports to include a Notice of Certification for ANDA No. 20-2101 under 21 U.S.C. § 355(j)(2)(B)(ii) and (iv) and 21 C.F.R. § 314.95(c)(6) as to the '796 patent.

45. Upon information and belief, Alembic Pharmaceuticals Ltd.'s tablet generic products will, if approved and marketed, infringe at least one claim of the '796 patent.

46. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Alembic Pharmaceuticals Ltd. has infringed at least one claim of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-2101 seeking approval to manufacture, use, sale, offer to sell and import Alembic Pharmaceuticals Ltd.'s tablet generic products before the expiration date of the '796 patent.

47. Upon information and belief, Alembic Pharmaceuticals Ltd.'s actions relating to Alembic Pharmaceuticals Ltd.'s ANDA No. 20-2101 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Alembic Limited, Alembic Global Holding SA and Alembic Pharmaceuticals Inc.

FOURTH COUNT FOR PATENT INFRINGEMENT

48. Otsuka realleges, and incorporates in full herein, paragraphs 29, 31, 32, 34 and 39-42.

49. Otsuka lists the '796 patent in the Orange Book for NDA No. 21-729.

50. Alembic Pharmaceuticals Ltd.'s letter purports to include a Notice of Certification for ANDA No. 20-2102 under 21 U.S.C. § 355(j)(2)(B)(ii) and (iv) and 21 C.F.R. § 314.95(c)(6) as to the '796 patent.

51. Upon information and belief, Alembic Pharmaceuticals Ltd.'s ODT generic products will, if approved and marketed, infringe at least one claim of the '796 patent.

52. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Alembic Pharmaceuticals Ltd. has infringed at least one claim of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-2102 seeking approval to manufacture, use, sale, offer to sell and import Alembic Pharmaceuticals Ltd.'s ODT generic products before the expiration date of the '796 patent.

53. Upon information and belief, Alembic Pharmaceuticals Ltd.'s actions relating to Alembic Pharmaceuticals Ltd.'s ANDA No. 20-2102 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Alembic Limited, Alembic Global Holding SA and Alembic Pharmaceuticals Inc.

FIFTH COUNT FOR PATENT INFRINGEMENT

54. Otsuka realleges, and incorporates in full herein, paragraphs 19, 21, 22 and 24.

55. The PTO issued the '760 patent on February 4, 2014, entitled "Low Hygroscopic Aripiprazole Drug Substance and Processes for the Preparation Thereof." A copy of the '760 patent is attached as Exhibit C.

56. Otsuka is the owner of the ’760 patent by virtue of assignment.

57. The ’760 patent expires on March 25, 2023 (including pediatric exclusivity).

58. The ’760 patent is directed to and claims, *inter alia*, aripiprazole drug substance.

59. Otsuka lists the ’760 patent in the Orange Book for NDA No. 21-436.

60. Alembic Pharmaceuticals Ltd.’s letter purports to include a Notice of Certification for ANDA No. 20-2101 under 21 U.S.C. § 355(j)(2)(B)(ii) and (iv) and 21 C.F.R. § 314.95(c)(6) as to the ’760 patent.

61. Upon information and belief, Alembic Pharmaceuticals Ltd.’s tablet generic products will, if approved and marketed, infringe at least one claim of the ’760 patent.

62. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Alembic Pharmaceuticals Ltd. has infringed at least one claim of the ’760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-2101 seeking approval to manufacture, use, sale, offer to sell and import Alembic Pharmaceuticals Ltd.’s tablet generic products before the expiration date of the ’760 patent.

63. Upon information and belief, Alembic Pharmaceuticals Ltd.’s actions relating to Alembic Pharmaceuticals Ltd.’s ANDA No. 20-2101 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Alembic Limited, Alembic Global Holding SA and Alembic Pharmaceuticals Inc.

SIXTH COUNT FOR PATENT INFRINGEMENT

64. Otsuka realleges, and incorporates in full herein, paragraphs 29, 31, 32, 34 and 55-58.

65. Otsuka lists the ’760 patent in the Orange Book for NDA No. 21-729.

66. Alembic Pharmaceuticals Ltd.'s letter purports to include a Notice of Certification for ANDA No. 20-2102 under 21 U.S.C. § 355(j)(2)(B)(ii) and (iv) and 21 C.F.R. § 314.95(c)(6) as to the '760 patent.

67. Upon information and belief, Alembic Pharmaceuticals Ltd.'s ODT generic products will, if approved and marketed, infringe at least one claim of the '760 patent.

68. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Alembic Pharmaceuticals Ltd. has infringed at least one claim of the '760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-2102 seeking approval to manufacture, use, sale, offer to sell and import Alembic Pharmaceuticals Ltd.'s ODT generic products before the expiration date of the '760 patent.

69. Upon information and belief, Alembic Pharmaceuticals Ltd.'s actions relating to Alembic Pharmaceuticals Ltd.'s ANDA No. 20-2102 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Alembic Limited, Alembic Global Holding SA and Alembic Pharmaceuticals Inc.

SEVENTH COUNT FOR PATENT INFRINGEMENT

70. Otsuka realleges, and incorporates in full herein, paragraphs 29, 31, 32 and 34.

71. The PTO issued the '421 patent on August 27, 2013, entitled "Flashmelt Oral Dosage Formulation." A copy of the '421 patent is attached as Exhibit D.

72. Otsuka is the owner of the '421 patent by virtue of assignment.

73. The '421 patent expires on July 24, 2021 (including pediatric exclusivity).

74. The '421 patent is directed to and claims, *inter alia*, flashmelt pharmaceutical dosage forms.

75. Otsuka lists the '421 patent in the Orange Book for NDA No. 21-729.

76. Alembic Pharmaceuticals Ltd.'s letter purports to include a Notice of Certification for ANDA No. 20-2102 under 21 U.S.C. § 355(j)(2)(B)(ii) and (iv) and 21 C.F.R. § 314.95(c)(6) as to the '421 patent.

77. Upon information and belief, Alembic Pharmaceuticals Ltd.'s ODT generic products will, if approved and marketed, infringe at least one claim of the '421 patent.

78. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Alembic Pharmaceuticals Ltd. has infringed at least one claim of the '421 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-2102 seeking approval to manufacture, use, sale, offer to sell and import Alembic Pharmaceuticals Ltd.'s ODT generic products before the expiration date of the '421 patent.

79. Upon information and belief, Alembic Pharmaceuticals Ltd.'s actions relating to Alembic Pharmaceuticals Ltd.'s ANDA No. 20-2102 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Alembic Limited, Alembic Global Holding SA and Alembic Pharmaceuticals Inc.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants Alembic Pharmaceuticals Ltd., Alembic Limited, Alembic Global Holding SA and Alembic Pharmaceuticals Inc. on the patent infringement claims set forth above and respectfully requests that this Court:

1) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Alembic has infringed at least one claim of the '615 patent through Alembic Pharmaceuticals Ltd.'s submission of ANDA No. 20-2101 to the FDA to obtain approval to manufacture, use, sale, offer to sell and import Alembic Pharmaceuticals Ltd.'s tablet generic products in the United States before the expiration of the '615 patent;

2) order that the effective date of any approval by the FDA of Alembic Pharmaceuticals Ltd.'s tablet generic products be a date that is not earlier than the expiration of the '615 patent, or such later date as the Court may determine;

3) enjoin Alembic from the manufacture, use, sale, offer to sell and import of Alembic Pharmaceuticals Ltd.'s tablet generic products until the expiration of the '615 patent, or such later date as the Court may determine;

4) enjoin Alembic and all persons acting in concert with Alembic, from seeking, obtaining or maintaining approval of Alembic Pharmaceuticals Ltd.'s ANDA No. 20-2101 until the expiration of the '615 patent;

5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Alembic has infringed at least one claim of the '615 patent through Alembic Pharmaceuticals Ltd.'s submission of ANDA No. 20-2102 to the FDA to obtain approval to manufacture, use, sale, offer to sell and import Alembic Pharmaceuticals Ltd.'s ODT generic products in the United States before the expiration of the '615 patent;

6) order that the effective date of any approval by the FDA of Alembic Pharmaceuticals Ltd.'s ODT generic products be a date that is not earlier than the expiration of the '615 patent, or such later date as the Court may determine;

7) enjoin Alembic from the manufacture, use, sale, offer to sell and import of Alembic Pharmaceuticals Ltd.'s ODT generic products until the expiration of the '615 patent, or such later date as the Court may determine;

8) enjoin Alembic and all persons acting in concert with Alembic, from seeking, obtaining or maintaining approval of Alembic Pharmaceuticals Ltd.'s ANDA No. 20-2102 until the expiration of the '615 patent;

9) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Alembic has infringed at least one claim of the '796 patent through Alembic Pharmaceuticals Ltd.'s submission of ANDA No. 20-2101 to the FDA to obtain approval to manufacture, use, sale, offer to sell and import Alembic Pharmaceuticals Ltd.'s generic products in the United States before the expiration of the '796 patent;

10) order that the effective date of any approval by the FDA of Alembic Pharmaceuticals Ltd.'s tablet generic products be a date that is not earlier than the expiration of the '796 patent, or such later date as the Court may determine;

11) enjoin Alembic from the manufacture, use, sale, offer to sell and import of Alembic Pharmaceuticals Ltd.'s tablet generic products until the expiration of the '796 patent, or such later date as the Court may determine;

12) enjoin Alembic and all persons acting in concert with Alembic, from seeking, obtaining or maintaining approval of Alembic Pharmaceuticals Ltd.'s ANDA No. 20-2101 until the expiration of the '796 patent;

13) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Alembic has infringed at least one claim of the '796 patent through Alembic Pharmaceuticals Ltd.'s submission of ANDA No. 20-2102 to the FDA to obtain approval to manufacture, use, sale, offer to sell and import Alembic Pharmaceuticals Ltd.'s ODT generic products in the United States before the expiration of the '796 patent;

14) order that the effective date of any approval by the FDA of Alembic Pharmaceuticals Ltd.'s ODT generic products be a date that is not earlier than the expiration of the '796 patent, or such later date as the Court may determine;

15) enjoin Alembic from the manufacture, use, sale, offer to sell and import of Alembic Pharmaceuticals Ltd.'s ODT generic products until the expiration of the '796 patent, or such later date as the Court may determine;

16) enjoin Alembic and all persons acting in concert with Alembic, from seeking, obtaining or maintaining approval of Alembic Pharmaceuticals Ltd.'s ANDA No. 20-2102 until the expiration of the '796 patent;

17) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Alembic has infringed at least one claim of the '760 patent through Alembic Pharmaceuticals Ltd.'s submission of ANDA No. 20-2101 to the FDA to obtain approval to manufacture, use, sale, offer to sell and import Alembic Pharmaceuticals Ltd.'s tablet generic products in the United States before the expiration of the '760 patent;

18) order that the effective date of any approval by the FDA of Alembic Pharmaceuticals Ltd.'s tablet generic products be a date that is not earlier than the expiration of the '760 patent, or such later date as the Court may determine;

19) enjoin Alembic from the manufacture, use, sale, offer to sell and import of Alembic Pharmaceuticals Ltd.'s tablet generic products until the expiration of the '760 patent, or such later date as the Court may determine;

20) enjoin Alembic and all persons acting in concert with Alembic, from seeking, obtaining or maintaining approval of Alembic Pharmaceuticals Ltd.'s ANDA No. 20-2101 until the expiration of the '760 patent;

21) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Alembic has infringed at least one claim of the '760 patent through Alembic Pharmaceuticals Ltd.'s submission of ANDA No. 20-2102 to the FDA to obtain approval to manufacture, use, sale, offer

to sell and import Alembic Pharmaceuticals Ltd.'s ODT generic products in the United States before the expiration of the '760 patent;

22) order that the effective date of any approval by the FDA of Alembic Pharmaceuticals Ltd.'s ODT generic products be a date that is not earlier than the expiration of the '760 patent, or such later date as the Court may determine;

23) enjoin Alembic from the manufacture, use, sale, offer to sell and import of Alembic Pharmaceuticals Ltd.'s ODT generic products until the expiration of the '760 patent, or such later date as the Court may determine;

24) enjoin Alembic and all persons acting in concert with Alembic, from seeking, obtaining or maintaining approval of Alembic Pharmaceuticals Ltd.'s ANDA No. 20-2102 until the expiration of the '760 patent;

25) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Alembic has infringed at least one claim of the '421 patent through Alembic Pharmaceuticals Ltd.'s submission of ANDA No. 20-2102 to the FDA to obtain approval to manufacture, use, sale, offer to sell and import Alembic Pharmaceuticals Ltd.'s ODT generic products in the United States before the expiration of the '421 patent;

26) order that the effective date of any approval by the FDA of Alembic Pharmaceuticals Ltd.'s ODT generic products be a date that is not earlier than the expiration of the '421 patent, or such later date as the Court may determine;

27) enjoin Alembic from the manufacture, use, sale, offer to sell and import of Alembic Pharmaceuticals Ltd.'s ODT generic products until the expiration of the '421 patent, or such later date as the Court may determine;

28) enjoin Alembic and all persons acting in concert with Alembic, from seeking, obtaining or maintaining approval of Alembic Pharmaceuticals Ltd.'s ANDA No. 20-2102 until the expiration of the '421 patent;

29) declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Otsuka costs, expenses and disbursements in this action, including reasonable attorney fees; and

30) award Otsuka such further and additional relief as this Court deems just and proper.

Respectfully submitted,

s/ John F. Brenner
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Dated: May 9, 2014

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