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Otsuka Pharmaceutical Co., Ltd.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD. Plaintiff, v. ALEMBIC PHARMACEUTICALS LIMITED, Defendant.	Civil Action No.: 14-cv-2982-JBS-KMW

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendant Alembic Pharmaceuticals Limited ("Alembic" or "Alembic Pharmaceuticals Ltd."), 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.

NATURE OF THE ACTION

3. 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, sell, offer to sell and import generic pharmaceutical products ("Alembic Pharmaceuticals Ltd.'s generic products") prior to the expirations of the asserted patents, as well as Alembic Pharmaceuticals Ltd.'s actual manufacture, use, sale, offer for sale and import of Alembic Pharmaceuticals Ltd.'s generic products upon approval of its ANDAs.

JURISDICTION AND VENUE

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

5. 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.

6. 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

7. 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.

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

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

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

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

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

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

14. 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, sell, 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.

15. 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.

16. 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.

17. 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.

18. 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.

SECOND COUNT FOR PATENT INFRINGEMENT

19. Otsuka realleges, and incorporates in full herein, paragraphs 7-10.

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

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

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

23. 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, sell, 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.

24. 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.

25. 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.

26. 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.

27. 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.

THIRD COUNT FOR PATENT INFRINGEMENT

28. Otsuka realleges, and incorporates in full herein, paragraphs 11, 13, 14 and 16.

29. 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.

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

31. The ’796 patent expires on March 25, 2023 (including pediatric exclusivity).

32. The ’796 patent is directed to and claims, *inter alia,* aripiprazole crystals.

33. Otsuka lists the ’796 patent in the Orange Book for NDA No. 21-436.

34. 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.

35. Upon information and belief, Alembic Pharmaceuticals Ltd.’s tablet generic products will, if approved and marketed, infringe claims 1-2 of the ’796 patent.

36. Upon information and belief, Alembic Pharmaceuticals Ltd.’s tablet generic products contain Anhydrous Aripiprazole Crystals B of low hygroscopicity as claimed in the ’796 patent.

37. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Alembic Pharmaceuticals Ltd. has infringed claims 1-2 of the ’796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-2101 seeking approval to manufacture, use, sell, offer to sell and import Alembic Pharmaceuticals Ltd.’s tablet generic products before the expiration date of the ’796 patent.

FOURTH COUNT FOR PATENT INFRINGEMENT

38. Otsuka realleges, and incorporates in full herein, paragraphs 28-37.

39. Alembic Pharmaceuticals Ltd.’s ANDA No. 20-2101 was approved by the FDA on April 28, 2015.

40. Upon information and belief, Alembic Pharmaceuticals Ltd. is currently manufacturing, marketing, importing, using, selling and offering for sale Alembic Pharmaceuticals Ltd.’s tablet generic products in connection with ANDA No. 20-2101.

41. Upon information and belief, Alembic Pharmaceuticals Ltd. is infringing claims 1-2 of the '796 patent under 35 U.S.C. § 271(a) by its manufacture, market, import, use, sale and offer for sale of Alembic Pharmaceuticals Ltd.'s tablet generic products.

FIFTH COUNT FOR PATENT INFRINGEMENT

42. Otsuka realleges, and incorporates in full herein, paragraphs 20, 22, 23, 25 and 29-32.

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

44. 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.

45. Upon information and belief, Alembic Pharmaceuticals Ltd.'s ODT generic products will, if approved and marketed, infringe claims 1-2 of the '796 patent.

46. Upon information and belief, Alembic Pharmaceuticals Ltd.'s ODT generic products contain Anhydrous Aripiprazole Crystals B of low hygroscopicity as claimed in the '796 patent.

47. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Alembic Pharmaceuticals Ltd. has infringed claims 1-2 of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-2102 seeking approval to manufacture, use, sell, offer to sell and import Alembic Pharmaceuticals Ltd.'s ODT generic products before the expiration date of the '796 patent.

SIXTH COUNT FOR PATENT INFRINGEMENT

48. Otsuka realleges, and incorporates in full herein, paragraphs 42-47.

49. Alembic Pharmaceuticals Ltd.'s ANDA No. 20-2102 was approved by the FDA on April 28, 2015.

50. Upon information and belief, Alembic Pharmaceuticals Ltd. is currently manufacturing, marketing, importing, using, selling and offering for sale Alembic Pharmaceuticals Ltd.'s ODT generic products in connection with ANDA No. 20-2102.

51. Upon information and belief, Alembic Pharmaceuticals Ltd. is infringing claims 1-2 of the '796 patent under 35 U.S.C. § 271(a) by its manufacture, market, import, use, sale and offer for sale of Alembic Pharmaceuticals Ltd.'s ODT generic products.

SEVENTH COUNT FOR PATENT INFRINGEMENT

52. Otsuka realleges, and incorporates in full herein, paragraphs 11, 13, 14 and 16.

53. 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.

54. Otsuka is the owner of the '760 patent by virtue of assignment.

55. The '760 patent expires on March 25, 2023 (including pediatric exclusivity).

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

57. Otsuka lists the '760 patent in the Orange Book for NDA No. 21-436.

58. 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.

59. Upon information and belief, Alembic Pharmaceuticals Ltd.'s tablet generic products will, if approved and marketed, infringe claims 1-2 of the '760 patent.

60. Alembic Pharmaceuticals Ltd.'s tablet generic products contain aripiprazole as the drug substance, as shown in the approved labeling for Alembic Pharmaceuticals Ltd.'s tablet generic products. *See* http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8d915e19-8c7e-46aa-a3af-3d293c65aba0 (accessed January 8, 2016).

61. Upon information and belief, the aripiprazole drug substance contained in Alembic Pharmaceuticals Ltd.'s tablet generic products is of low hygroscopicity as claimed in the '760 patent.

62. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Alembic Pharmaceuticals Ltd. has infringed claims 1-2 of the '760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-2101 seeking approval to manufacture, use, sell, offer to sell and import Alembic Pharmaceuticals Ltd.'s tablet generic products before the expiration date of the '760 patent.

EIGHTH COUNT FOR PATENT INFRINGEMENT

63. Otsuka realleges, and incorporates in full herein, paragraphs 52-62.

64. Alembic Pharmaceuticals Ltd.'s ANDA No. 20-2101 was approved by the FDA on April 28, 2015.

65. Upon information and belief, Alembic Pharmaceuticals Ltd. is currently manufacturing, marketing, importing, using, selling and offering for sale Alembic Pharmaceuticals Ltd.'s tablet generic products in connection with ANDA No. 20-2101.

66. Upon information and belief, Alembic Pharmaceuticals Ltd. is infringing claims 1-2 of the '760 patent under 35 U.S.C. § 271(a) by its manufacture, market, import, use, sale and offer for sale of Alembic Pharmaceuticals Ltd.'s tablet generic products.

NINTH COUNT FOR PATENT INFRINGEMENT

67. Otsuka realleges, and incorporates in full herein, paragraphs 20, 22, 23, 25 and 53-57.

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

69. 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.

70. Upon information and belief, Alembic Pharmaceuticals Ltd.’s ODT generic products will, if approved and marketed, infringe claims 1-2 of the ’760 patent.

71. Alembic Pharmaceuticals Ltd.’s ODT generic products contain aripiprazole as the drug substance, as shown in the approved labeling for Alembic Pharmaceuticals Ltd.’s ODT generic products. *See* http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4467f79a-6a10-4710-959a-a229f4345a46 (accessed January 8, 2016).

72. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Alembic Pharmaceuticals Ltd. has infringed claims 1-2 of the ’760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 20-2102 seeking approval to manufacture, use, sell, offer to sell and import Alembic Pharmaceuticals Ltd.’s ODT generic products before the expiration date of the ’760 patent.

TENTH COUNT FOR PATENT INFRINGEMENT

73. Otsuka realleges, and incorporates in full herein, paragraphs 67-72.

74. Alembic Pharmaceuticals Ltd.’s ANDA No. 20-2102 was approved by the FDA on April 28, 2015.

75. Upon information and belief, Alembic Pharmaceuticals Ltd. is currently manufacturing, marketing, importing, using, selling and offering for sale Alembic Pharmaceuticals Ltd.'s ODT generic products in connection with ANDA No. 20-2102.

76. Upon information and belief, Alembic Pharmaceuticals Ltd. is infringing claims 1-2 of the '760 patent under 35 U.S.C. § 271(a) by its manufacture, market, import, use, sale and offer for sale of Alembic Pharmaceuticals Ltd.'s ODT generic products.

ELEVENTH COUNT FOR PATENT INFRINGEMENT

77. Otsuka realleges, and incorporates in full herein, paragraphs 20, 22, 23 and 25.

78. 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.

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

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

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

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

83. 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.

84. Upon information and belief, Alembic Pharmaceuticals Ltd.'s ODT generic products are flashmelt formulations containing the medicament aripiprazole.

85. Upon information and belief, Alembic Pharmaceuticals Ltd.'s ODT generic products contain superdisintegrants, dispersing agents, binders and distributing agents as required by the '421 patent claims, or their equivalents.

86. Upon information and belief, Alembic Pharmaceuticals Ltd.'s ODT generic products are made with the same or equivalent formulations as claimed in the '421 patent.

87. Upon information and belief, Alembic Pharmaceuticals Ltd.'s ODT generic products will, if approved and marketed, infringe claims 1-17 of the '421 patent.

88. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Alembic Pharmaceuticals Ltd. has infringed claims 1-17 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.

TWELFTH COUNT FOR PATENT INFRINGEMENT

89. Otsuka realleges, and incorporates in full herein, paragraphs 77-88.

90. Alembic Pharmaceuticals Ltd.'s ANDA No. 20-2102 was approved by the FDA on April 28, 2015.

91. Upon information and belief, Alembic Pharmaceuticals Ltd. is currently manufacturing, marketing, importing, using, selling and offering for sale Alembic Pharmaceuticals Ltd.'s ODT generic products in connection with ANDA No. 20-2102.

92. Upon information and belief, Alembic Pharmaceuticals Ltd. is infringing claims 1-17 of the '421 patent under 35 U.S.C. § 271(a) by its manufacture, market, import, use, sale and offer for sale of Alembic Pharmaceuticals Ltd.'s ODT generic products.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendant Alembic Pharmaceuticals Ltd. 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, sell, 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 for sale 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, sell, 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 for sale 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, sell, 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 for sale 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(a), Alembic Pharmaceuticals Ltd. has infringed at least one claim of the '796 patent through Alembic Pharmaceuticals Ltd.'s manufacture, market, import, use, sale and offer for sale of Alembic

Pharmaceuticals Ltd.'s tablet generic products in the United States before the expiration of the '796 patent;

14) award Otsuka all available and legally permissible damages sufficient to compensate Otsuka for Alembic Pharmaceuticals Ltd.'s infringement of the '796 patent by its manufacture, market, import, use, sale and offer for sale of Alembic Pharmaceuticals Ltd.'s tablet generic products, together with interest, in an amount to be determined at trial;

15) 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, sell, offer to sell and import Alembic Pharmaceuticals Ltd.'s ODT generic products in the United States before the expiration of the '796 patent;

16) 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;

17) enjoin Alembic from the manufacture, use, sale, offer for sale 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;

18) 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;

19) enter judgment that, under 35 U.S.C. § 271(a), Alembic Pharmaceuticals Ltd. has infringed at least one claim of the '796 patent through Alembic Pharmaceuticals

Ltd.'s manufacture, market, import, use, sale and offer for sale of Alembic Pharmaceuticals Ltd.'s ODT generic products in the United States before the expiration of the '796 patent;

20) award Otsuka all available and legally permissible damages sufficient to compensate Otsuka for Alembic Pharmaceuticals Ltd.'s infringement of the '796 patent by its manufacture, market, import, use, sale and offer for sale of Alembic Pharmaceuticals Ltd.'s ODT generic products, together with interest, in an amount to be determined at trial;

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. 20-2101 to the FDA to obtain approval to manufacture, use, sell, offer to sell and import Alembic Pharmaceuticals Ltd.'s tablet 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 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;

23) enjoin Alembic from the manufacture, use, sale, offer for sale 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;

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

25) enter judgment that, under 35 U.S.C. § 271(a), Alembic Pharmaceuticals Ltd. has infringed at least one claim of the '760 patent through Alembic Pharmaceuticals Ltd.'s manufacture, market, import, use, sale and offer for sale of Alembic Pharmaceuticals Ltd.'s tablet generic products in the United States before the expiration of the '760 patent;

26) award Otsuka all available and legally permissible damages sufficient to compensate Otsuka for Alembic Pharmaceuticals Ltd.'s infringement of the '760 patent by its manufacture, market, import, use, sale and offer for sale of Alembic Pharmaceuticals Ltd.'s tablet generic products, together with interest, in an amount to be determined at trial;

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

28) 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;

29) enjoin Alembic from the manufacture, use, sale, offer for sale 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;

30) 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;

31) enter judgment that, under 35 U.S.C. § 271(a), Alembic Pharmaceuticals Ltd. has infringed at least one claim of the '760 patent through Alembic Pharmaceuticals Ltd.'s manufacture, market, import, use, sale and offer for sale of Alembic Pharmaceuticals Ltd.'s ODT generic products in the United States before the expiration of the '760 patent;

32) award Otsuka all available and legally permissible damages sufficient to compensate Otsuka for Alembic Pharmaceuticals Ltd.'s infringement of the '760 patent by its manufacture, market, import, use, sale and offer for sale of Alembic Pharmaceuticals Ltd.'s ODT generic products, together with interest, in an amount to be determined at trial;

33) 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, sell, offer to sell and import Alembic Pharmaceuticals Ltd.'s ODT generic products in the United States before the expiration of the '421 patent;

34) 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;

35) enjoin Alembic from the manufacture, use, sale, offer for sale 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;

36) 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;

37) enter judgment that, under 35 U.S.C. § 271(a), Alembic Pharmaceuticals Ltd. has infringed at least one claim of the '421 patent through Alembic Pharmaceuticals Ltd.'s manufacture, market, import, use, sale and offer for sale of Alembic Pharmaceuticals Ltd.'s ODT generic products in the United States before the expiration of the '421 patent;

38) award Otsuka all available and legally permissible damages sufficient to compensate Otsuka for Alembic Pharmaceuticals Ltd.'s infringement of the '421 patent by its manufacture, market, import, use, sale and offer for sale of Alembic Pharmaceuticals Ltd.'s ODT generic products, together with interest, in an amount to be determined at trial;

39) find Alembic Pharmaceuticals Ltd.'s infringement to have been willful and award Otsuka enhanced damages for this willful infringement;

40) 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

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

Date: March 23, 2016

Respectfully submitted,

s/ Melissa A. Chuderewicz
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