

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD.,)	
)	
Plaintiff,)	
)	
v.)	
)	Civil Action No.:
ORCHID PHARMA LTD., ORCHID)	
HEALTHCARE, ORCHID PHARMA, INC.)	
and ORGENUS PHARMA INC.,)	
)	
Defendants.)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. (“Otsuka”), by way of Complaint against Defendants Orchid Pharma Ltd. (f/k/a Orchid Chemicals & Pharmaceuticals Limited) (“Orchid Pharma Ltd.”), Orchid Healthcare (a Division of Orchid Pharma Ltd.) (“Orchid Healthcare”), Orchid Pharma, Inc. (“Orchid Pharma”) and Orgenus Pharma Inc. (“Orgenus Pharma”) (collectively, “Defendants”), 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, Orchid Pharma Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Orchid Towers, 313 Valluvar Kottam High Road, Nungambakkam, Chennai 600034, Tamil Nadu, India.

3. Upon information and belief, Orchid Healthcare is an unincorporated division of Orchid Pharma Ltd., organized and existing under the laws of India, maintaining a place of business at Plot Nos. B5(Pt.) & B6(Pt.), SIPCOT Industrial Park, Irungattukottai, Sriperumbudur 602105, Kancheepuram District, Tamil Nadu, India.

4. Upon information and belief, Orchid Pharma is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 100 Overlook Center, 2nd Floor, Princeton, NJ 08540. Upon information and belief, Orchid Pharma Ltd. is the parent company of Orchid Pharma.

5. Upon information and belief, Orgenus Pharma is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 100 Overlook Center, 2nd Floor, Princeton, NJ 08540. Upon information and belief, Orchid Pharma Ltd. is the parent company of Orgenus Pharma.

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 Orchid Healthcare’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, import, offer to sell and sell generic pharmaceutical products (“Defendants’ generic products”) prior to the expiration of the asserted patents.

JURISDICTION AND VENUE

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

8. This Court has jurisdiction over Orchid Pharma Ltd. Upon information and belief, Orchid Pharma Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic products. Upon information and belief, Orchid Pharma Ltd., directly or through its subsidiaries, affiliates and/or agents, including Orchid Healthcare, Orgenus Pharma and Orchid Pharma, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Orchid Pharma Ltd. has submitted, or caused to be submitted, at least 46 ANDAs and 76 Drug Master Files to the FDA. *See* http://orchidpharma.com/downloads/annualreports/orchid_ar_15.pdf (accessed January 12, 2016). Upon information and belief, Orchid Pharma Ltd. is registered to do business in New Jersey under Business I.D. No. 0100883141. Orchid Pharma Ltd. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

9. This Court has jurisdiction over Orchid Healthcare. Upon information and belief, Orchid Healthcare is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Orchid Healthcare, directly or indirectly, manufactures, markets, imports and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Orchid Healthcare purposefully has conducted and continues to conduct business, directly or indirectly, in this judicial district and this judicial district is a likely destination of Defendants' generic products. Orchid Healthcare has previously submitted to the jurisdiction of this Court and has

further previously availed itself of this Court by asserting counterclaims in another civil action initiated in this jurisdiction.

10. Upon information and belief, this Court additionally has jurisdiction over Orchid Healthcare because it has availed itself of the rights and benefits of this judicial district, having stated in a purported Offer of Confidential Access, dated December 9, 2015, that “[t]his Offer of Confidential Access Agreement shall be governed by the laws of the State of New Jersey.”

11. This Court has jurisdiction over Orchid Pharma. Upon information and belief, Orchid Pharma is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Orchid Pharma, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and this judicial district. Upon information and belief, Orchid Pharma is Orchid Pharma Ltd.’s “US Generic Sales and Marketing Company.” *See* http://orchidpharma.com/worldwide_operations.aspx#subsidiaries (accessed January 20, 2016). Upon information and belief, Orchid Pharma is registered as a manufacturer and wholesaler in the State of New Jersey (No. 5003961) under the trade name “Karalex Pharma, LLC.” *See* New Jersey Drug Registration and Verification, at <http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdList.aspx> (accessed January 20, 2016).

12. This Court has jurisdiction over Orgenus Pharma. Upon information and belief, Orgenus Pharma is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Orgenus Pharma, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Orgenus Pharma “provides all business development and operational services” for Orchid Pharma Ltd.,

including filing Drug Master Files and ANDAs with the FDA and “represent[ing] [Orchid Pharma Ltd.] for all matters relating to the review and approval of such filings by the FDA[.]” See http://orchidpharma.com/downloads/annualreports/orchid_ar_15.pdf (accessed January 20, 2016).

13. Upon information and belief, Orchid Pharma Ltd., Orchid Healthcare, Orchid Pharma and Orgenus Pharma operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States including in this judicial district. According to Orchid Pharma Ltd.’s website, it is a “[v]ertically integrated global pharmaceutical company” with “[e]stablished research, manufacturing and marketing capabilities” and “[f]ully integrated API and Finished Dosage Form product offerings.” See http://www.orchidpharma.com/ir_factsheet.aspx (accessed January 19, 2016). Upon information and belief, Orchid Pharma and Orgenus Pharma share a common corporate director.

14. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(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, Orchid Healthcare submitted ANDA No. 202683 to the FDA, under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to manufacture, use, import, offer to sell and sell generic products containing 2, 5, 10, 15, 20 and 30 mg of aripiprazole (“Defendants’ tablet generic products”) in the United States.

23. Otsuka received a letter from Orchid Healthcare, dated December 9, 2015, purporting to include a Notice of Certification for ANDA No. 202683 under 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) as to the ’615 patent. Otsuka also received a letter from Orchid Healthcare dated December 9, 2015, purporting to include a Notice of Certification for ANDA No. 202547 under 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) as to the ’615 patent. Both letters are referred to collectively herein as “Orchid Healthcare’s letter.”

24. Orchid Healthcare’s letter alleges that the active ingredient in Defendants’ tablet generic products for which it seeks approval is aripiprazole.

25. Upon information and belief, Defendants’ 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), Orchid Healthcare has infringed at least one claim of the ’615 patent by submitting, or causing to be submitted to

the FDA, ANDA No. 202683 seeking approval to manufacture, use, import, offer to sell and sell Defendants' tablet generic products before the expiration date of the '615 patent.

27. Upon information and belief, Orchid Healthcare's actions relating to Orchid Healthcare's ANDA No. 202683 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Orchid Pharma Ltd., Orchid Healthcare, Orchid Pharma and Orgenus Pharma.

SECOND COUNT FOR PATENT INFRINGEMENT

28. Otsuka realleges, and incorporates in full herein, paragraphs 15-18, 23.

29. Otsuka is the holder of NDA No. 21-279 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. Upon information and belief, Orchid Healthcare submitted ANDA No. 202547 to the FDA, under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to manufacture, use, import, offer to sell and sell generic products containing 10 and 15 mg of aripiprazole ("Defendants' ODT generic products") in the United States.

32. Orchid Healthcare's letter purports to include a Notice of Certification for ANDA No. 202547 under 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) as to the '615 patent.

33. Orchid Healthcare's letter alleges that the active ingredient in Defendants' ODT generic products for which it seeks approval is aripiprazole.

34. Upon information and belief, Defendants' ODT generic products will, if approved and marketed, infringe at least one claim of the '615 patent.

35. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Orchid Healthcare has infringed at least one claim of the '615 patent by submitting, or causing to be submitted to

the FDA, ANDA No. 202547 seeking approval to manufacture, use, import, offer to sell and sell Defendants' ODT generic products before the expiration date of the '615 patent.

36. Upon information and belief, Orchid Healthcare's actions relating to Orchid Healthcare's ANDA No. 202547 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Orchid Pharma Ltd., Orchid Healthcare, Orchid Pharma and Orgenus Pharma.

THIRD COUNT FOR PATENT INFRINGEMENT

37. Otsuka realleges, and incorporates in full herein, paragraphs 19, 21-24.

38. 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.

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

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

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

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

43. Orchid Healthcare's letter purports to include a Notice of Certification for ANDA No. 202683 under 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) as to the '796 patent.

44. Upon information and belief, Defendants' tablet generic products will, if approved and marketed, infringe at least one claim of the '796 patent.

45. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Orchid Healthcare has infringed at least one claim of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 202683 seeking approval to manufacture, use, import, offer to sell and sell Defendants' tablet generic products before the expiration date of the '796 patent.

46. Upon information and belief, Orchid Healthcare's actions relating to Orchid Healthcare's ANDA No. 202683 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Orchid Pharma Ltd., Orchid Healthcare, Orchid Pharma and Orgenus Pharma.

FOURTH COUNT FOR PATENT INFRINGEMENT

47. Otsuka realleges, and incorporates in full herein, paragraphs 23, 29, 31, 33 and 38-41.

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

49. Orchid Healthcare's letter purports to include a Notice of Certification for ANDA No. 202547 under 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) as to the '796 patent.

50. Upon information and belief, Defendants' ODT generic products will, if approved and marketed, infringe at least one claim of the '796 patent.

51. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Orchid Healthcare has infringed at least one claim of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 202547 seeking approval to manufacture, use, import, offer to sell and sell Defendants' ODT generic products before the expiration date of the '796 patent.

52. Upon information and belief, Orchid Healthcare's actions relating to Orchid Healthcare's ANDA No. 202547 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Orchid Pharma Ltd., Orchid Healthcare, Orchid Pharma and Orgenus Pharma.

FIFTH COUNT FOR PATENT INFRINGEMENT

53. Otsuka realleges, and incorporates in full herein, paragraphs 19, 21-24.

54. 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.

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

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

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

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

59. Orchid Healthcare's letter purports to include a Notice of Certification for ANDA No. 202683 under 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) as to the '760 patent.

60. Upon information and belief, Defendants' tablet generic products will, if approved and marketed, infringe at least one claim of the '760 patent.

61. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Orchid Healthcare has infringed at least one claim of the '760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 202683 seeking approval to manufacture, use, import, offer to sell and sell Defendants' tablet generic products before the expiration date of the '760 patent.

62. Upon information and belief, Orchid Healthcare's actions relating to Orchid Healthcare's ANDA No. 202683 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Orchid Pharma Ltd., Orchid Healthcare, Orchid Pharma and Orgenus Pharma.

SIXTH COUNT FOR PATENT INFRINGEMENT

63. Otsuka realleges, and incorporates in full herein, paragraphs 23, 29, 31, 33 and 54-57.

64. Otsuka lists the '760 patent in the Orange Book for NDA No. 21-729.

65. Orchid Healthcare's letter purports to include a Notice of Certification for ANDA No. 202547 under 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) as to the '760 patent.

66. Upon information and belief, Defendants' ODT generic products will, if approved and marketed, infringe at least one claim of the '760 patent.

67. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Orchid Healthcare has infringed at least one claim of the '760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 202547 seeking approval to manufacture, use, import, offer to sell and sell Defendants' ODT generic products before the expiration date of the '760 patent.

68. Upon information and belief, Orchid Healthcare's actions relating to Orchid Healthcare's ANDA No. 202547 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Orchid Pharma Ltd., Orchid Healthcare, Orchid Pharma and Orgenus Pharma.

SEVENTH COUNT FOR PATENT INFRINGEMENT

69. Otsuka realleges, and incorporates in full herein, paragraphs 23, 29, 31 and 33.

70. 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.

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

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

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

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

75. Orchid Healthcare's letter purports to include a Notice of Certification for ANDA No. 202547 under 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c) as to the '421 patent.

76. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Orchid Healthcare has infringed at least one claim of the '421 patent by submitting, or causing to be submitted to the FDA, ANDA No. 202547 seeking approval to manufacture, use, import, offer to sell and sell Defendants' ODT generic products before the expiration date of the '421 patent.

77. Upon information and belief, Orchid Healthcare's actions relating to Orchid Healthcare's ANDA No. 202547 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Orchid Pharma Ltd., Orchid Healthcare, Orchid Pharma and Orgenus Pharma.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Defendants 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), Defendants have infringed at least one claim of the '615 patent through Orchid Healthcare's submission of ANDA No. 202683 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' 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 Defendants' 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 Defendants from the manufacture, use, import, offer for sale and sale of Defendants' tablet generic products until the expiration of the '615 patent, or such later date as the Court may determine;
- 4) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Orchid Healthcare's ANDA No. 202683 until expiration of the '615 patent;
- 5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '615 patent through Orchid Healthcare's submission of ANDA No. 202547 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' 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 Defendants' 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 Defendants from the manufacture, use, import, offer for sale and sale of Defendants' ODT generic products until the expiration of the '615 patent, or such later date as the Court may determine;
- 8) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Orchid Healthcare's ANDA No. 202547 until expiration of the '615 patent;
- 9) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '796 patent through Orchid Healthcare's submission of ANDA No. 202683 to the FDA to obtain approval to manufacture, use, import,

offer to sell and sell Defendants' tablet 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 Defendants' 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 Defendants from the manufacture, use, import, offer for sale and sale of Defendants' tablet generic products until the expiration of the '796 patent, or such later date as the Court may determine;
- 12) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Orchid Healthcare's ANDA No. 202683 until expiration of the '796 patent;
- 13) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '796 patent through Orchid Healthcare's submission of ANDA No. 202547 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' 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 Defendants' 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 Defendants from the manufacture, use, import, offer for sale and sale of Defendants' ODT generic products until the expiration of the '796 patent, or such later date as the Court may determine;

- 16) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Orchid Healthcare's ANDA No. 202547 until expiration of the '796 patent;
- 17) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '760 patent through Orchid Healthcare's submission of ANDA No. 202683 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' 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 Defendants' 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 Defendants from the manufacture, use, import, offer for sale and sale of Defendants' tablet generic products until the expiration of the '760 patent, or such later date as the Court may determine;
- 20) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Orchid Healthcare's ANDA No. 202683 until expiration of the '760 patent;
- 21) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '760 patent through Orchid Healthcare's submission of ANDA No. 202547 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' 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 Defendants' 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 Defendants from the manufacture, use, import, offer for sale and sale of Defendants' ODT generic products until the expiration of the '760 patent, or such later date as the Court may determine;
- 24) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Orchid Healthcare's ANDA No. 202547 until expiration of the '760 patent;
- 25) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim of the '421 patent through Orchid Healthcare's submission of ANDA No. 202547 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Defendants' 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 Defendants' 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 Defendants from the manufacture, use, import, offer for sale and sale of Defendants' ODT generic products until the expiration of the '421 patent, or such later date as the Court may determine;
- 28) enjoin Defendants and all persons acting in concert with Defendants, from seeking, obtaining or maintaining approval of Orchid Healthcare's ANDA No. 202547 until 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/ Melissa A. Chuderewicz
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