

business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, NJ 08536. Upon information and belief, Macleods USA is a wholly-owned subsidiary of Macleods Pharmaceuticals.

NATURE OF THE ACTION

4. 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. 8,759,350 (“the ’350 patent”), arising under the United States patent laws, Title 35, United States Code, § 100 *et seq.*, including 35 U.S.C. §§ 271 and 281, and for a declaratory judgment of infringement of the ’350 patent under 28 U.S.C. §§ 2201 and 2202. This action relates to Macleods Pharmaceuticals’ filing of an Abbreviated New Drug Application (“ANDA”) 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 (“Macleods’ generic products”) prior to the expiration of the asserted patents.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a), 2201 and 2202.

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

products. Upon information and belief, Macleods Pharmaceuticals is a “truly . . . global pharmaceutical company.” *See* <http://www.macleodspharma.com/default.asp>. Upon information and belief, Macleods Pharmaceuticals’ website states that “Macleods has received FDA approval on 9 [ANDAs] and has another 60 filed and awaiting approval.” *See* <http://www.macleodspharma.com/UnitedStates.asp>.

7. Upon information and belief, this Court additionally has jurisdiction over Macleods Pharmaceuticals because it has availed itself of the rights and benefits of this judicial district, having stated in a purported Offer of Confidential Access, dated May 18, 2015, that “[t]his Agreement shall be governed and construed in accordance with the laws of the State of New Jersey without regard to its conflicts-of-law rules.”

8. This Court has jurisdiction over Macleods USA. Upon information and belief, Macleods USA is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Macleods USA, directly or indirectly, manufactures, imports, markets and sells generic drug products throughout the United States and in this judicial district. Upon information and belief, Macleods USA is registered as a wholesaler in the State of New Jersey (No. 5004370). *See* New Jersey Registration and Verification, at <http://web.doh.state.nj.us/apps2FoodDrugLicense/fdList.aspx>.

9. Upon information and belief, Macleods Pharmaceuticals and Macleods USA 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. Upon information and belief, Macleods Pharmaceuticals is “a vertically integrated global pharmaceutical company” with “more than 10,000 professionally qualified employees across the globe.” *See* <http://www.macleodspharma.com/default.asp>.

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

FIRST COUNT FOR PATENT INFRINGEMENT

11. 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.

12. Otsuka is the owner of the ’615 patent by virtue of assignment.

13. The ’615 patent expires on December 16, 2024 (including pediatric exclusivity).

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

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

16. Otsuka lists the ’615 patent in Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) for NDA No. 21-436.

17. Otsuka markets aripiprazole tablets in the United States under the trademark Abilify[®].

18. Upon information and belief, Macleods Pharmaceuticals submitted ANDA No. 204111 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 Macleods’ generic products in the United States.

19. Otsuka received a letter from Macleods Pharmaceuticals dated May 18, 2015, purporting to include a Notice of Certification for ANDA No. 204111 under 21 U.S.C. § 355(j)(2)(B)(ii) (“Macleods Pharmaceuticals’ 204111 letter”) as to the ’615 patent.

20. Macleods Pharmaceuticals’ 204111 letter alleges that it seeks “approval to engage in the commercial manufacture, use, or sale of aripiprazole tablets (‘Macleods’ ANDA Product’).”

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

22. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Macleods Pharmaceuticals has infringed at least one claim of the '615 patent by submitting, or causing to be submitted to the FDA, ANDA No. 204111 seeking approval to manufacture, use, import, offer to sell and sell Macleods' generic products before the expiration date of the '615 patent.

23. Upon information and belief, Macleods Pharmaceuticals' actions relating to Macleods Pharmaceuticals' ANDA No. 204111 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Macleods Pharmaceuticals and Macleods USA.

SECOND COUNT FOR PATENT INFRINGEMENT

24. Otsuka realleges, and incorporates in full herein, paragraphs 15-20.

25. 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.

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

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

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

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

30. Macleods Pharmaceuticals' 204111 letter purports to include a Notice of Certification for ANDA No. 204111 under 21 U.S.C. § 355(j)(2)(B)(ii) as to the '796 patent.

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

32. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Macleods Pharmaceuticals has infringed at least one claim of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 204111 seeking approval to manufacture, use, import, offer to sell and sell Macleods' generic products before the expiration date of the '796 patent.

33. Upon information and belief, Macleods Pharmaceuticals' actions relating to Macleods Pharmaceuticals' ANDA No. 204111 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Macleods Pharmaceuticals and Macleods USA.

THIRD COUNT FOR PATENT INFRINGEMENT

34. Otsuka realleges, and incorporates in full herein, paragraphs 15-20.

35. 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.

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

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

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

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

40. Macleods Pharmaceuticals' 204111 letter purports to include a Notice of Certification for ANDA No. 204111 under 21 U.S.C. § 355(j)(2)(B)(ii) as to the '760 patent.

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

42. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Macleods has infringed at least one claim of the '760 patent by submitting, or causing to be submitted to the FDA, ANDA

No. 204111 seeking approval to manufacture, use, import, offer to sell and sell Macleods' generic products before the expiration date of the '760 patent.

43. Upon information and belief, Macleods Pharmaceuticals' actions relating to Macleods Pharmaceuticals' ANDA No. 204111 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Macleods Pharmaceuticals and Macleods USA.

FOURTH COUNT FOR PATENT INFRINGEMENT

44. Otsuka realleges, and incorporates in full herein, paragraphs 15-20.

45. The PTO issued the '350 patent on June 24, 2014, entitled "Carbostyryl Derivatives and Serotonin Reuptake Inhibitors for Treatment of Mood Disorders." A copy of the '350 patent is attached as Exhibit D.

46. Otsuka is the owner of the '350 patent by virtue of assignment.

47. The '350 patent expires on March 2, 2027, subject to any supplemental patent term adjustment.

48. The '350 patent is directed to and claims, inter alia, pharmaceutical compositions and methods of treatment.

49. Otsuka lists the '350 patent in the Orange Book for NDA No. 21-436.

50. Upon information and belief, Macleods has actual knowledge of the '350 patent.

51. Upon information and belief, Macleods' generic products will, if approved and marketed, infringe at least one claim of the '350 patent.

52. Upon information and belief, the label for Macleods' generic products will recommend, suggest, encourage and/or instruct others to use Macleods' generic products in a manner that infringes at least one claim of the '350 patent.

53. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Macleods Pharmaceuticals has infringed at least one claim of the '350 patent by submitting, or causing to be submitted to the FDA, ANDA No. 204111 seeking approval to manufacture, use, import, offer to sell and sell Macleods' generic products before the expiration date of the '350 patent.

54. Upon information and belief, Macleods Pharmaceuticals' actions relating to Macleods Pharmaceuticals' ANDA No. 204111 complained of herein were done with the cooperation, participation, assistance, and for the benefit, of Macleods Pharmaceuticals and Macleods USA.

**FIFTH COUNT FOR DECLARATORY JUDGMENT
OF PATENT INFRINGEMENT**

55. Otsuka realleges, and incorporates in full herein, paragraphs 15-20 and 45-54.

56. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

57. There is an actual and justiciable controversy between Otsuka and Macleods concerning infringement of the '350 patent of sufficient immediacy and reality such that the Court may entertain Otsuka's request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

58. Macleods has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Macleods' generic products prior to expiration of the '350 patent.

59. Macleods's actions, including, but not limited to, submitting, or causing to be submitted to the FDA, ANDA No. 204111 seeking approval to manufacture, use, import, offer to sell and sell Macleods' generic products before the expiration date of the '350 patent and engaging in litigation, indicate a refusal to change the course of their actions in the face of knowledge of the '350 patent and acts by Otsuka.

60. Upon information and belief, Macleods seeks immediate approval of its ANDA No. 204111 from the FDA.

61. Upon information and belief, Macleods intends to manufacture, use, offer for sale, sell and/or import Macleods' generic products upon FDA approval of ANDA No. 204111.

62. Any commercial manufacture, use, offer for sale, sale and/or importation of Macleods' generic products prior to the expiration of the '350 patent will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '350 patent under 35 U.S.C. §§ 271(a)-(c).

63. Otsuka will be irreparably harmed by Macleods' infringing activities unless those activities are enjoined by this Court.

64. Otsuka does not have an adequate remedy at law.

65. Otsuka is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Macleods' generic products prior to expiration of the '350 patent by Macleods will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '350 patent.

WHEREFORE, Plaintiff Otsuka respectfully requests that the Court enter judgment in its favor and against Macleods 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), Macleods has infringed at least one claim of the '615 patent through Macleods Pharmaceuticals' submission of ANDA No. 204111 to the FDA to obtain approval to manufacture, use, offer to sell and sell Macleods' 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 Macleods' 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 Macleods from the manufacture, use, import, offer for sale and sale of Macleods' generic products until the expiration of the '615 patent, or such later date as the Court may determine;
- 4) enjoin Macleods and all persons acting in concert with Macleods, from seeking, obtaining or maintaining approval of Macleods Pharmaceuticals' ANDA No. 204111 until expiration of the '615 patent;
- 5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Macleods has infringed at least one claim of the '796 patent through Macleods Pharmaceuticals' submission of ANDA No. 204111 to the FDA to obtain approval to manufacture, use, offer to sell and sell Macleods' generic products in the United States before the expiration of the '796 patent;
- 6) order that the effective date of any approval by the FDA of Macleods' 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;
- 7) enjoin Macleods from the manufacture, use, import, offer for sale and sale of Macleods' generic products until the expiration of the '796 patent, or such later date as the Court may determine;
- 8) enjoin Macleods and all persons acting in concert with Macleods, from seeking, obtaining or maintaining approval of Macleods Pharmaceuticals' ANDA No. 204111 until expiration of the '796 patent;

- 9) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Macleods has infringed at least one claim of the '760 patent through Macleods Pharmaceuticals' submission of ANDA No. 204111 to the FDA to obtain approval to manufacture, use, offer to sell and sell Macleods' generic products in the United States before the expiration of the '760 patent;
- 10) order that the effective date of any approval by the FDA of Macleods' 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;
- 11) enjoin Macleods from the manufacture, use, import, offer for sale and sale of Macleods' generic products until the expiration of the '760 patent, or such later date as the Court may determine;
- 12) enjoin Macleods and all persons acting in concert with Macleods, from seeking, obtaining or maintaining approval of Macleods Pharmaceuticals' ANDA No. 204111 until expiration of the '760 patent;
- 13) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Macleods has infringed at least one claim of the '350 patent through Macleods Pharmaceuticals' submission of ANDA No. 204111 to the FDA to obtain approval to manufacture, use, offer to sell and sell Macleods' generic products in the United States before the expiration of the '350 patent;
- 14) order that the effective date of any approval by the FDA of Macleods' generic products be a date that is not earlier than the expiration of the '350 patent, or such later date as the Court may determine;

- 15) enjoin Macleods from the manufacture, use, import, offer for sale and sale of Macleods' generic products until the expiration of the '350 patent, or such later date as the Court may determine;
- 16) enjoin Macleods and all persons acting in concert with Macleods, from seeking, obtaining or maintaining approval of Macleods Pharmaceuticals' ANDA No. 204111 until expiration of the '350 patent;
- 17) declare and enter judgment under 28 U.S.C. §§ 2201 and 2202 that any future commercial manufacture, use, offer for sale, sale and/or importation of Macleods' generic products prior to expiration of the '350 patent by Macleods will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '350 patent under 35 U.S.C. §§ 271(a)-(c);
- 18) order that, if Macleods engages in the commercial manufacture, use, sale, offer for sale or importation of Macleods' generic products before the expiration of the '350 patent, a judgment be awarded to Otsuka for damages resulting from such infringement, together with interest, in an amount to be determined at trial;
- 19) 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
- 20) award Otsuka such further and additional relief as this Court deems just and proper.

Date: July 2, 2015

Respectfully submitted,

s/ Melissa A. Chuderewicz
Melissa A. Chuderewicz
chuderem@pepperlaw.com
PEPPER HAMILTON LLP
(A Pennsylvania Limited Liability Partnership)
Suite 400

301 Carnegie Center
Princeton, New Jersey 08543
(609) 452-0808
Attorneys for Plaintiff
Otsuka Pharmaceutical Co., Ltd.

Of counsel:

James B. Monroe
Paul W. Browning
Denise Main
FINNEGAN, HENDERSON,
FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, N.W.
Washington, DC 20001-4413
(202) 408-4000