Melissa A. Chuderewicz
PEPPER HAMILTON LLP
(A Pennsylvania Limited Liability Partnership)
Suite 400
301 Carnegie Center
Princeton, New Jersey 08543-5276
Phone: (609) 452-4808
chuderem@pepperlaw.com

Attorneys for Plaintiff
Otsuka Pharmaceutical Co., Ltd

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD., Plaintiff, v. MYLAN INC. and MYLAN PHARMACEUTICALS INC., Defendants.	Civil Action No.: 14-cv-4508-JBS-KMW

AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka"), by way of Complaint against Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") (collectively, "Mylan"), 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, Mylan Inc. is a corporation organized and existing under the laws of Pennsylvania, having its principal place of business at 1000 Mylan Blvd., Canonsburg, PA 15317.

3. Upon information and belief, Mylan Pharmaceuticals is a corporation organized and existing under the laws of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505. Upon information or belief, Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc.

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"), U.S. Patent No. 7,053,092 ("the '092 patent"), U.S. Patent No. 8,642,600 ("the '600 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 Mylan 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, sale, offer to sell and import generic pharmaceutical products ("Mylan Pharmaceuticals' 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, 1338(a), 2201 and 2202.

6. This Court has jurisdiction over Mylan Inc. Upon information and belief, Mylan Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Mylan Inc., directly or through its subsidiaries, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. According to Mylan Inc.'s 10-K Report, filed February 27, 2014, Mylan "is a leading global pharmaceutical company which develops, licenses, manufactures, markets and distributes generic, branded generic and specialty pharmaceuticals," "had 324 ANDAs pending FDA approval" as of December 31, 2013, and "holds the number one ranking in the U.S. generics prescription market in terms of sales and the number two ranking in terms of prescriptions dispensed." Upon information and belief, Mylan's website states that "[o]ne out of every 11 U.S. prescriptions dispensed, brand name or generic, is filled with a Mylan product." *See* http://www.mylan.com/businesses/generic-products. Upon information and belief, Mylan Inc. owns a subsidiary, Mylan Specialty, located at 110 Allen Rd., Basking Ridge, NJ 07920. Upon information and belief, Mylan Inc. is registered (No. 5003762) as a Manufacturer and Wholesaler in the State of New Jersey. Upon information and belief, Mylan Inc. is registered (Entity ID 0100971292) with the State of New Jersey Division of Revenue and Enterprise Services. Mylan Inc. 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.

7. This Court has jurisdiction over Mylan Pharmaceuticals. Upon information and belief, Mylan Pharmaceuticals is in the business of manufacturing, marketing, importing and

selling pharmaceutical drug products, including generic drug products. Upon information and belief, Mylan Pharmaceuticals, directly or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Mylan Pharmaceuticals purposefully has conducted and continues to conduct business, directly or indirectly, in this judicial district, and this judicial district is the likely destination of Mylan Pharmaceuticals' generic products. According to Mylan Inc.'s 10-K Report, dated February 27, 2013, Mylan Pharmaceuticals is Mylan's "primary U.S. pharmaceutical research, development, manufacturing, marketing and distribution subsidiary[.]" Upon information and belief, Mylan Pharmaceuticals is registered (Entity ID 0100214277) with the State of New Jersey Division of Revenue and Enterprise Services. Mylan Pharmaceuticals 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.

8. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals, 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, Mylan Inc. describes Mylan Inc. and its subsidiaries as a company "with true vertical integration." *See* http://www.mylan.com/company/about-us.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § l400(b).

FIRST COUNT FOR PATENT INFRINGEMENT

10. 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.

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

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

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

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

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

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

17. Upon information and belief, Mylan Pharmaceuticals submitted ANDA No. 206-240 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 Mylan Pharmaceuticals' generic products in the United States.

18. Otsuka received a letter from Mylan Pharmaceuticals dated May 28, 2014, purporting to include a Notice of Certification for ANDA No. 206-240 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 ("Mylan Pharmaceuticals' 206-240 letter") as to the '615 patent.

19. Mylan Pharmaceuticals' 206-240 letter alleges that the name of the drug product that is subject of the Mylan ANDA is aripiprazole oral tablets.

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

21. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals has infringed at least one claim of the '615 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206-240 seeking approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' generic products before the expiration date of the '615 patent.

22. Upon information and belief, Mylan Pharmaceuticals' actions relating to ANDA No. 206-240 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Mylan Inc. and Mylan Pharmaceuticals.

SECOND COUNT FOR PATENT INFRINGEMENT

23. Otsuka realleges, and incorporates in full herein, paragraphs 14-19.

24. 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.

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

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

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

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

29. Mylan Pharmaceuticals' 206-240 letter purports to include a Notice of Certification for ANDA No. 206-240 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '796 patent.

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

31. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals has infringed at least one claim of the '796 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206-240 seeking approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' generic products before the expiration date of the '796 patent.

32. Upon information and belief, Mylan Pharmaceuticals' actions relating to ANDA No. 206-240 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Mylan Inc. and Mylan Pharmaceuticals.

THIRD COUNT FOR PATENT INFRINGEMENT

33. Otsuka realleges, and incorporates in full herein, paragraphs 14-19.

34. 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.

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

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

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

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

39. Mylan Pharmaceuticals' 206-240 letter purports to include a Notice of Certification for ANDA No. 206-240 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '760 patent.

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

41. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals has infringed at least one claim of the '760 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206-240 seeking approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' generic products before the expiration date of the '760 patent.

42. Upon information and belief, Mylan Pharmaceuticals' actions relating to ANDA No. 206-240 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Mylan Inc. and Mylan Pharmaceuticals.

FOURTH COUNT FOR PATENT INFRINGEMENT

43. Otsuka realleges, and incorporates in full herein, paragraphs 14-19.

44. The PTO issued the '092 patent on May 30, 2006, entitled "5-HT1A Receptor Subtype Agonist." A copy of the '092 patent is attached as Exhibit D.

45. Otsuka is the owner of the '092 patent by virtue of assignment.

46. The '092 patent expires on January 28, 2022.

47. The '092 patent is directed to and claims, *inter alia*, methods of treatment comprising administering aripiprazole.

48. Otsuka lists the '092 patent in the Orange Book for NDA No. 21-436.

49. Mylan Pharmaceuticals' 206-240 letter purports to include a Notice of Certification for ANDA No. 206-240 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '092 patent.

50. Upon information and belief, Mylan Pharmaceuticals' generic products will, if approved and marketed, infringe at least one claim of the '092 patent.

51. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals has infringed at least one claim of the '092 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206-240 seeking approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' generic products before the expiration date of the '092 patent.

52. Upon information and belief, Mylan Pharmaceuticals' actions relating to ANDA No. 206-240 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Mylan Inc. and Mylan Pharmaceuticals.

FIFTH COUNT FOR PATENT INFRINGEMENT

53. Otsuka realleges, and incorporates in full herein, paragraphs 14-19.

54. The PTO issued the '600 patent on February 4, 2014, entitled "Method of Treating Autism." A copy of the '600 patent is attached as Exhibit E.

55. Otsuka is the owner of the '600 patent by virtue of assignment.

56. The '600 patent expires on July 28, 2022 (including pediatric exclusivity).

57. The '600 patent is directed to and claims, *inter alia*, methods of treatment comprising administering aripiprazole.

58. Otsuka lists the '600 patent in the Orange Book for NDA No. 21-436.

59. Mylan Pharmaceuticals' 206-240 letter purports to include a Notice of Certification for ANDA No. 206-240 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 as to the '600 patent.

60. Upon information and belief, Mylan Pharmaceuticals' generic products will, if approved and marketed, infringe at least one claim of the '600 patent.

61. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals has infringed at least one claim of the '600 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206-240 seeking approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' generic products before the expiration date of the '600 patent.

62. Upon information and belief, Mylan Pharmaceuticals' actions relating to ANDA No. 206-240 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Mylan Inc. and Mylan Pharmaceuticals.

SIXTH COUNT FOR PATENT INFRINGEMENT

63. Otsuka realleges, and incorporates in full herein, paragraphs 14-19.

64. The U.S. Patent and Trademark Office ("PTO") issued the '350 patent on June 24, 2014, entitled "Carbostyril Derivatives and Serotonin Reuptake Inhibitors for Treatment of Mood Disorders." A copy of the '350 patent is attached as Exhibit F.

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

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

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

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

69. Upon information and belief, Mylan has actual knowledge of the '350 patent.

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

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

72. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Mylan Pharmaceuticals has infringed at least one claim of the '350 patent by submitting, or causing to be submitted to the FDA, ANDA No. 206-240 seeking approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' generic products before the expiration date of the '350 patent.

73. Upon information and belief, Mylan Pharmaceuticals' actions relating to ANDA No. 206-240 complained of herein were done with the cooperation, participation and assistance, and for the benefit, of Mylan Inc. and Mylan Pharmaceuticals.

SEVENTH COUNT FOR DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

74. Otsuka realleges, and incorporates in full herein, paragraphs 14-19 and 64-73.

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

76. There is an actual and justiciable controversy between Otsuka and Mylan 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.

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

78. Mylan's actions, including, but not limited to, submitting, or causing to be submitted to the FDA, ANDA No. 206-240 seeking approval to manufacture, use, import, offer to sell and sell Mylan's 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.

79. Upon information and belief, the FDA may approve Mylan's ANDA No. 206-240 as early as the April 20, 2015, expiration of the Pediatric Exclusivity period associated with U.S. Patent No. 5,006,528.

80. Upon information and belief, Mylan intends to manufacture, use, offer for sale, sell and/or import Mylan's generic products upon FDA approval of ANDA No. 206-240.

81. Any commercial manufacture, use, offer for sale, sale and/or importation of Mylan's 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).

82. Otsuka will be irreparably harmed by Mylan's infringing activities unless those activities are enjoined by this Court.

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

84. Otsuka is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Mylan's generic products prior to expiration of the

'350 patent by Mylan 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 Defendants Mylan Inc. and Mylan Pharmaceuticals. 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), Mylan has infringed at least one claim of the '615 patent through Mylan Pharmaceuticals' submission of ANDA No. 206-240 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' 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 Mylan Pharmaceuticals' 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 Mylan from the manufacture, use, import, offer for sale and sale of Mylan Pharmaceuticals' generic products until the expiration of the '615 patent, or such later date as the Court may determine;

4) enjoin Mylan and all persons acting in concert with Mylan, from seeking, obtaining or maintaining approval of Mylan Pharmaceuticals' ANDA No. 206-240 until expiration of the '615 patent;

5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Mylan has infringed at least one claim of the '796 patent through Mylan Pharmaceuticals' submission of ANDA No. 206-240 to the FDA to obtain approval to manufacture, use, import, offer to sell

and sell Mylan Pharmaceuticals' 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 Mylan Pharmaceuticals' 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 Mylan from the manufacture, use, import, offer for sale and sale of Mylan Pharmaceuticals' generic products until the expiration of the '796 patent, or such later date as the Court may determine;

8) enjoin Mylan and all persons acting in concert with Mylan, from seeking, obtaining or maintaining approval of Mylan Pharmaceuticals' ANDA No. 206-240 until expiration of the '796 patent;

9) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Mylan has infringed at least one claim of the '760 patent through Mylan Pharmaceuticals' submission of ANDA No. 206-240 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' 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 Mylan Pharmaceuticals' 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 Mylan from the manufacture, use, import, offer for sale and sale of Mylan Pharmaceuticals' generic products until the expiration of the '760 patent, or such later date as the Court may determine;

12) enjoin Mylan and all persons acting in concert with Mylan, from seeking, obtaining or maintaining approval of Mylan Pharmaceuticals' ANDA No. 206-240 until expiration of the '760 patent;

13) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Mylan has infringed at least one claim of the '092 patent through Mylan Pharmaceuticals' submission of ANDA No. 206-240 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' generic products in the United States before the expiration of the '092 patent;

14) order that the effective date of any approval by the FDA of Mylan Pharmaceuticals' generic products be a date that is not earlier than the expiration of the '092 patent, or such later date as the Court may determine;

15) enjoin Mylan from the manufacture, use, import, offer for sale and sale of Mylan Pharmaceuticals' generic products until the expiration of the '092 patent, or such later date as the Court may determine;

16) enjoin Mylan and all persons acting in concert with Mylan, from seeking, obtaining or maintaining approval of Mylan Pharmaceuticals' ANDA No. 206-240 until expiration of the '092 patent;

17) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Mylan has infringed at least one claim of the '600 patent through Mylan Pharmaceuticals' submission of ANDA No. 206-240 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' generic products in the United States before the expiration of the '600 patent;

18) order that the effective date of any approval by the FDA of Mylan Pharmaceuticals' generic products be a date that is not earlier than the expiration of the '600 patent, or such later date as the Court may determine;

19) enjoin Mylan from the manufacture, use, import, offer for sale and sale of Mylan Pharmaceuticals' generic products until the expiration of the '600 patent, or such later date as the Court may determine;

20) enjoin Mylan and all persons acting in concert with Mylan, from seeking, obtaining or maintaining approval of Mylan Pharmaceuticals' ANDA No. 206-240 until expiration of the '600 patent;

21) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Mylan has infringed at least one claim of the '350 patent through Mylan Pharmaceuticals' submission of ANDA No. 206-240 to the FDA to obtain approval to manufacture, use, import, offer to sell and sell Mylan Pharmaceuticals' generic products in the United States before the expiration of the '350 patent;

22) order that the effective date of any approval by the FDA of Mylan Pharmaceuticals' 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;

23) enjoin Mylan from the manufacture, use, import, offer for sale and sale of Mylan Pharmaceuticals' generic products until the expiration of the '350 patent, or such later date as the Court may determine;

24) enjoin Mylan and all persons acting in concert with Mylan, from seeking, obtaining or maintaining approval of Mylan Pharmaceuticals' ANDA No. 206-240 until expiration of the '350 patent;

25) 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 Mylan's generic products prior to expiration of the '350 patent by Mylan will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '350 patent under 35 U.S.C. §§ 271(a)-(c);

26) order that, if Mylan engages in the commercial manufacture, use, sale, offer for sale or importation of Mylan's 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;

27) 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

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

Dated: April 7, 2015

Respectfully submitted,

s/Melissa A. Chuderewicz
Melissa A. Chuderewicz
PEPPER HAMILTON LLP
(A Pennsylvania Limited Liability Partnership)
Suite 400
301 Carnegie Center
Princeton, New Jersey 08543-5276
Phone: (609) 452-4808
chuderem@pepperlaw.com

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