IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S, Plaintiffs, v. HETERO LABS LTD., HETERO LABS LTD. UNIT-V, HETERO USA, INC., HETERO DRUGS LTD. AND HONOUR LAB LTD., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively, "Plaintiffs"), by way of Complaint against Defendants Hetero Labs Ltd., Hetero Labs Ltd. Unit-V, Hetero USA, Inc., Hetero Drugs Ltd. and Honour Lab Ltd. (collectively, "Hetero"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 7,888,362 ("the '362 patent"), 8,349,840 ("the '840 patent"), 8,618,109 ("the '109 patent"), 9,839,637 ("the '637 patent"), and 10,307,419 ("the '419 patent") (collectively, "patents in suit"), 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 Hetero's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to engage in the commercial manufacture, use or sale of generic pharmaceutical products before the expiration of the patents in

suit.

THE PARTIES

2. 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.

3. Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Otsuka has granted Lundbeck an exclusive license to the '362, '840, '109, '637 and '419 patents.

4. Otsuka and Lundbeck are engaged in the business of researching, developing and bringing to market innovative pharmaceutical products.

5. Upon information and belief, Hetero Drugs Ltd. is a corporation organized under the laws of India and its principal place of business is located at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

6. Upon information and belief, Hetero Labs Ltd. is a corporation organized under the laws of India and its principal place of business is located at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

7. Upon informtaion and belief, Hetero Labs Ltd. Unit-V is a division of Hetero Labs Ltd. and its principal place of business is located at Polepally, Jadcherla, Mahabubnagar 509 301, Andhra Pradesh, India.

8. Upon information and belief, Hetero USA, Inc. is a corporation organized under the laws of Delaware and its principal place of business is located at 1035 Centennial Avenue, Piscataway, NJ 08854. Upon information and belief, Hetero USA, Inc. is the U.S. Regulatory Agent for Hetero Labs Limited Unit-V, Hetero Labs Ltd. and Hetero Drugs Ltd.

9. Upon information and belief, Hetero Drugs Ltd. and Hetero Labs Ltd. each own a 50% share of Hetero USA, Inc.

10. Upon information and belief, Honour Lab Ltd. is a corporation organized under the laws of India and its principal place of business is located at 8-3-166/7/1, Hetero House, Erragadda, Hyderabad 500 018, Telangana, India.

11. Upon information and belief, Honour Lab Ltd. is a subsidiary or affiliate of the Hetero group companies, including Hetero Drugs Ltd. and Hetero Labs Ltd.

JURISDICTION AND VENUE

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

13. This Court has personal jurisdiction over Hetero Drugs Ltd. Upon information and belief, Hetero Drugs Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Hetero Drugs Ltd. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Hetero Labs Ltd. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

14. Upon information and belief, Hetero Drugs Ltd. admits it "is one of India's leading generic pharmaceutical companies" and it "has a strong global presence in over 126 countries[.]" https://www.heteroworld.com/company-profile.php (accessed Oct. 12, 2019). Upon information and belief, Hetero Drugs Ltd. admits "our R&D has been able to develop niche generics, . . . ANDAs and FTFs[.]" https://www.heteroworld.com/research.php (accessed Oct. 12, 2019).

15. This Court has personal jurisdiction over Hetero Labs Ltd. Upon information and belief, Hetero Labs Ltd. is in the business of manufacturing, marketing, importing and selling

pharmaceutical drug products, including generic drug products. Upon information and belief, Hetero Labs Ltd. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Hetero Labs Ltd. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

16. Upon information and belief, Hetero Labs Ltd. "is a research based global pharmaceutical company focused on development, manufacturing and marketing of Active Pharmaceutical Ingredients (APIs), Intermediate Chemicals & Finished Dosages." https://www.indiamart.com/heterolabs-limited/aboutus.html (Hetero Labs Ltd. Profile, accessed Oct. 12, 2019).

17. Upon information and belief, Hetero Drugs Ltd. and Hetero Labs Ltd. share more than one common corporate director. *See* https://www.zaubacorp.com/company/HETERO-DRUGS-LIMITED/U24230TG1993PLC015582 (Hetero Drugs Ltd. Profile, accessed Oct. 12, 2019); https://www.zaubacorp.com/company/HETERO-LABS-LIMITED/U24110TG1989PLC009723 (Hetero Labs Ltd. Profile, accessed Oct. 12, 2019) (naming five common corporate directors).

18. This Court has personal jurisdiction over Hetero Labs Ltd. Unit-V. Upon information and belief, Hetero Labs Ltd. Unit-V is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Hetero Labs Ltd. Unit-V directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Hetero Labs Ltd. Unit-V purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's

generic products.

19. Upon information and belief, Hetero Labs Ltd. Unit-V is the drug manufacturing facility for Hetero Labs Ltd. and manufactures Hetero's generic products. *See, e.g.*, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/hetero-labs-limited-unit-v-520359-08152017 (letter from the FDA to Hetero Labs Ltd. Unit-V, accessed Oct. 12, 2019).

20. This Court has personal jurisdiction over Hetero USA, Inc. Upon information and belief, Hetero USA, Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Hetero USA, Inc. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Hetero USA, Inc. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

21. Upon information and belief, Hetero USA, Inc. admits it is "the US representation of HETERO, a privately owned; research based global pharmaceutical company" and that it has "a significant presence in the development and marketing of finished dosages (comprising of various dosage forms of wide range of therapeutic categories), active pharmaceutical ingredients (API's), over-the-counter products." https://www.linkedin.com/company/hetero-usa-inc/about/ (Hetero USA, Inc. LinkedIn Profile, accessed Oct. 12, 2019).

22. This Court has personal jurisdiction over Honour Lab Ltd. Upon information and belief, Honour Lab Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Honour Lab Ltd. directly, or indirectly, develops, manufactures, markets and sells generic drugs

throughout the United States and in this judicial district. Upon information and belief, Honour Lab Ltd. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products.

23. Upon information and belief, Honour Lab Ltd. is the holder of FDA Drug Master File No. 32532 for brexpiprazole.

24. Upon information and belief, Honour Lab Ltd. is vertically integrated with Hetero Drugs Ltd., Hetero Labs Ltd., Hetero Labs Ltd. Unit-V and Hetero USA, Inc. *See, e.g.*, https://www.indiamart.com/heterolabs-limited/aboutus.html ("Hetero is building on the strengths of vertical integration in discovery research, process chemistry, API manufacturing, formulation development and commercialization.") (accessed Oct. 12, 2019). Upon information and belief, Honour Lab Ltd. is engaged in manufacturing drug products which are primarily supplied to Hetero Labs Ltd. and other companies within the Hetero group of companies. http://pharma.industry-report.net/honour-lab-ltd/ (accessed Oct. 12, 2019). Upon information and belief, Hetero Drugs Ltd., Hetero Labs Ltd. and Honour Lab Ltd. share one or more common corporate directors. *See* https://www.zaubacorp.com/company/HONOUR-LAB-LIMITED/U24233TG2011PLC077561 (Honour Lab Ltd. Profile, accessed Oct. 12, 2019); https://www.zaubacorp.com/company/HETERO-DRUGS-LIMITED/U24230TG1993PLC015582 (Hetero Drugs Ltd. Profile, accessed Oct. 12, 2019); https://www.zaubacorp.com/company/HETERO-LABS-LIMITED/U24110TG1989PLC009723 (Hetero Labs Ltd. Profile, accessed Oct. 12, 2019).

25. Upon information and belief, Hetero Drugs Ltd., Hetero Labs Ltd., Hetero Labs Ltd. Unit-V, Hetero USA, Inc. and Honour Lab Ltd. hold themselves out as a unitary entity and 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.

26. Hetero's ANDA filing regarding the patents in suit relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Hetero's intent to market and sell Hetero's generic products in this judicial district.

27. Hetero has taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—which, upon information and belief, will be purposefully directed at the District of Delaware and elsewhere throughout the United States. Upon information and belief, Hetero intends to direct sales of its generic drugs in this judicial district, among other places, once Hetero receives the requested FDA approval to market its generic products. Upon information and belief, Hetero will engage in marketing of its proposed generic products in Delaware upon approval of its ANDA.

28. Upon information and belief, Hetero has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 213669.

29. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Hetero Drugs Ltd. and Hetero Labs Ltd. are incorporated in India and may be sued in any judicial district.

30. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Hetero Labs Ltd. Unit-V is a division of Hetero Labs Ltd., which is incorporated in India and may be sued in any judicial district.

31. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Hetero USA, Inc. is incorporated in the state of Delaware.

FACTUAL BACKGROUND

The NDA

32. Otsuka is the holder of New Drug Application ("NDA") No. 205422 for REXULTI® (brexpiprazole) Tablets in 0.25, 0.5, 1, 2, 3, and 4 mg dosage forms ("REXULTI® Tablets").

33. The FDA approved NDA No. 205422 on July 10, 2015.

34. REXULTI® Tablets are prescription drugs approved for the adjunctive treatment of major depressive disorder and the treatment of schizophrenia. Brexpiprazole is the active ingredient in REXULTI® Tablets.

The Patents In Suit

35. The United States Patent and Trademark Office ("the PTO") issued the '362 patent on February 15, 2011, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders." A true and correct copy of the '362 patent is attached as Exhibit A.

36. Otsuka owns the '362 patent through assignment as recorded by the PTO at Reel 048501, Frame 0122; Reel 021939, Frame 0746 and Reel 048501, Frame 0166.

37. The '362 patent currently expires on April 12, 2026, by virtue of a terminal disclaimer filed in the PTO that disclaimed the 317 days of patent term adjustment granted to the '362 patent under 35 U.S.C. § 154(b). A true and correct copy of the terminal disclaimer is attached as Exhibit B.

38. Otsuka filed a Submission Pursuant to 37 C.F.R. § 1.765 for Patent Term Extension Application Under 35 U.S.C. § 156 and Response to Notice of Final Determination, which is attached as Exhibit C. In Exhibit C, Otsuka requests an extension under 35 U.S.C. § 156(c) of 986

days. Accordingly, the '362 patent will expire on December 23, 2028, if granted the 986 days of Patent Term Extension under 35 U.S.C. § 156(c).

39. The '362 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

40. The PTO issued the '840 patent on January 8, 2013, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders." A true and correct copy of the '840 patent is attached as Exhibit D.

41. Otsuka owns the '840 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.

42. The '840 patent is subject to a terminal disclaimer and expires on April 12, 2026.

43. The '840 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

44. The PTO issued the '109 patent on December 31, 2013, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders." A true and correct copy of the '109 patent is attached as Exhibit E.

45. Otsuka owns the '109 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.

46. The '109 patent is subject to a terminal disclaimer and expires on April 12, 2026.

47. The '109 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

48. The PTO issued the ’637 patent on December 12, 2017, entitled “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders.” A true and correct copy of the ’637 patent is attached as Exhibit F.

49. Otsuka owns the ’637 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.

50. The ’637 patent is subject to a terminal disclaimer and expires on April 12, 2026.

51. The ’637 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

52. The PTO issued the ’419 patent on June 4, 2019, entitled “Tablet Comprising 7-[4-(4-benzo[b]thiopen-4-yl-piperazine-1-yl)butoxy]-1H-quinolin-2-one or a Salt Thereof.” A true and correct copy of the ’419 patent is attached as Exhibit G.

53. Otsuka owns the ’419 patent through assignment as recorded by the PTO at Reel 033930, Frame 0447.

54. The ’419 patent expires on October 12, 2032.

55. The ’419 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

The ANDA

56. Upon information and belief, Hetero filed ANDA No. 213669 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use or sale in the United States of brexpiprazole tablets, 0.25, 0.5, 1, 2, 3, and 4 mg (“Hetero’s generic products”), which are generic versions of Otsuka’s REXULTI® (brexpiprazole) Tablets.

57. Upon information and belief, ANDA No. 213669 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“paragraph IV certifications”), alleging that the claims of the

patents in suit are invalid, unenforceable and/or would not be infringed by Hetero's generic products.

58. Otsuka received a letter sent by Hetero, dated September 11, 2019, purporting to be a "Notice of Certification" for ANDA No. 213669 ("Hetero's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Hetero's Notice Letter notified Otsuka that Hetero had filed ANDA No. 213669, seeking approval to engage in the commercial manufacture, use or sale of Hetero's generic products before the expiration of the patents in suit.

59. Plaintiffs commenced this action within 45 days of receiving Hetero's September 11, 2019, Notice Letter.

COUNT I

(INFRINGEMENT OF THE '362 PATENT)

60. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

61. Upon information and belief, Hetero filed ANDA No. 213669 seeking approval to manufacture, use, import, offer to sell and/or sell Hetero's generic products in the United States before the expiration of the '362 patent.

62. Upon information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '362 patent are invalid, unenforceable and/or not infringed.

63. Upon information and belief, in its ANDA No. 213669, Hetero has represented to the FDA that Hetero's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

64. Hetero has actual knowledge of Otsuka's '362 patent, as evidenced by Hetero's September 11, 2019, Notice Letter.

65. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Hetero has infringed one or more claims of the '362 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213669, seeking approval to commercially manufacture, use, import, offer to sell or sell Hetero's generic products before the expiration date of the '362 patent.

66. Upon information and belief, if ANDA No. 213669 is approved, Hetero intends to and will offer to sell, sell and/or import in the United States Hetero's generic products.

67. Upon information and belief, if ANDA No. 213669 is approved, Hetero will infringe one or more claims of the '362 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Hetero's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213669 shall be no earlier than the expiration of the '362 patent and any additional periods of exclusivity.

68. Upon information and belief, Hetero's actions relating to Hetero's ANDA No. 213669 complained of herein were done by and for the benefit of Hetero.

69. Plaintiffs will be irreparably harmed by Hetero's infringing activities unless this Court enjoins those activities.

70. Plaintiffs do not have an adequate remedy at law.

COUNT II

(INFRINGEMENT OF THE '840 PATENT)

71. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

72. Upon information and belief, Hetero filed ANDA No. 213669 seeking approval to manufacture, use, import, offer to sell and/or sell Hetero's generic products in the United States before the expiration of the '840 patent.

73. Upon information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '840 patent are invalid, unenforceable and/or not infringed.

74. Upon information and belief, in its ANDA No. 213669, Hetero has represented to the FDA that Hetero's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

75. Hetero has actual knowledge of Otsuka's '840 patent, as evidenced by Hetero's September 11, 2019, Notice Letter.

76. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Hetero has infringed one or more claims of the '840 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213669, seeking approval to commercially manufacture, use, import, offer to sell or sell Hetero's generic products before the expiration date of the '840 patent.

77. Upon information and belief, if ANDA No. 213669 is approved, Hetero will infringe one or more claims of the '840 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Hetero's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213669 shall be no earlier than the expiration of the '840 patent and any additional periods of exclusivity.

78. Upon information and belief, Hetero knows, should know and intends that physicians will prescribe and patients will take Hetero's generic products for which approval is sought in ANDA No. 213669, and therefore will infringe at least one claim of the '840 patent.

79. Upon information and belief, Hetero has knowledge of the '840 patent and, by its proposed package insert for Hetero's generic products, knows or should know that it will induce direct infringement of at least one claim of the '840 patent, either literally or under the doctrine of equivalents.

80. Upon information and belief, Hetero is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Hetero's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '840 patent.

81. Upon information and belief, if ANDA No. 213669 is approved, Hetero intends to and will offer to sell, sell and/or import in the United States Hetero's generic products.

82. Upon information and belief, Hetero's actions relating to Hetero's ANDA No. 213669 complained of herein were done by and for the benefit of Hetero.

83. Plaintiffs will be irreparably harmed by Hetero's infringing activities unless this Court enjoins those activities.

84. Plaintiffs do not have an adequate remedy at law.

COUNT III

(INFRINGEMENT OF THE '109 PATENT)

85. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

86. Upon information and belief, Hetero filed ANDA No. 213669 seeking approval to manufacture, use, import, offer to sell and/or sell Hetero's generic products in the United States before the expiration of the '109 patent.

87. Upon information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '109 patent are invalid, unenforceable and/or not infringed.

88. Upon information and belief, in its ANDA No. 213669, Hetero has represented to the FDA that Hetero's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

89. Hetero has actual knowledge of Otsuka's '109 patent, as evidenced by Hetero's September 11, 2019, Notice Letter.

90. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Hetero has infringed one or more claims of the '109 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213669, seeking approval to commercially manufacture, use, import, offer to sell or sell Hetero's generic products before the expiration date of the '109 patent.

91. Upon information and belief, if ANDA No. 213669 is approved, Hetero will infringe one or more claims of the '109 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Hetero's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213669 shall be no earlier than the expiration of the '109 patent and any additional periods of exclusivity.

92. Upon information and belief, Hetero knows, should know and intends that physicians will prescribe and patients will take Hetero's generic products for which approval is sought in ANDA No. 213669, and therefore will infringe at least one claim of the '109 patent.

93. Upon information and belief, Hetero has knowledge of the '109 patent and, by its proposed package insert for Hetero's generic products, knows or should know that it will induce direct infringement of at least one claim of the '109 patent, either literally or under the doctrine of equivalents.

94. Upon information and belief, Hetero is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Hetero's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '109 patent.

95. Upon information and belief, if ANDA No. 213669 is approved, Hetero intends to and will offer to sell, sell and/or import in the United States Hetero's generic products.

96. Upon information and belief, Hetero's actions relating to Hetero's ANDA No. 213669 complained of herein were done by and for the benefit of Hetero.

97. Plaintiffs will be irreparably harmed by Hetero's infringing activities unless this Court enjoins those activities.

98. Plaintiffs do not have an adequate remedy at law.

COUNT IV

(INFRINGEMENT OF THE '637 PATENT)

99. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

100. Upon information and belief, Hetero filed ANDA No. 213669 seeking approval to manufacture, use, import, offer to sell and/or sell Hetero's generic products in the United States before the expiration of the '637 patent.

101. Upon information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '637 patent are invalid, unenforceable and/or not infringed.

102. Upon information and belief, in its ANDA No. 213669, Hetero has represented to the FDA that Hetero's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

103. Hetero has actual knowledge of Otsuka's '637 patent, as evidenced by Hetero's September 11, 2019, Notice Letter.

104. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Hetero has infringed one or more claims of the '637 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213669, seeking approval to commercially manufacture, use, import, offer to sell or sell Hetero's generic products before the expiration date of the '637 patent.

105. Upon information and belief, if ANDA No. 213669 is approved, Hetero will infringe one or more claims of the '637 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Hetero's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213669 shall be no earlier than the expiration of the '637 patent and any additional periods of exclusivity.

106. Upon information and belief, Hetero knows, should know and intends that

physicians will prescribe and patients will take Hetero's generic products for which approval is sought in ANDA No. 213669, and therefore will infringe at least one claim of the '637 patent.

107. Upon information and belief, Hetero has knowledge of the '637 patent and, by its proposed package insert for Hetero's generic products, knows or should know that it will induce direct infringement of at least one claim of the '637 patent, either literally or under the doctrine of equivalents.

108. Upon information and belief, Hetero is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Hetero's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '637 patent.

109. Upon information and belief, if ANDA No. 213669 is approved, Hetero intends to and will offer to sell, sell and/or import in the United States Hetero's generic products.

110. Upon information and belief, Hetero's actions relating to Hetero's ANDA No. 213669 complained of herein were done by and for the benefit of Hetero.

111. Plaintiffs will be irreparably harmed by Hetero's infringing activities unless this Court enjoins those activities.

112. Plaintiffs do not have an adequate remedy at law.

COUNT V

(INFRINGEMENT OF THE '419 PATENT)

113. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

114. Upon information and belief, Hetero filed ANDA No. 213669 seeking approval to manufacture, use, import, offer to sell and/or sell Hetero's generic products in the United States

before the expiration of the ’419 patent.

115. Upon information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the ’419 patent are invalid, unenforceable and/or not infringed.

116. Upon information and belief, in its ANDA No. 213669, Hetero has represented to the FDA that Hetero’s generic products are pharmaceutically and therapeutically equivalent to Otsuka’s REXULTI® Tablets.

117. Hetero has actual knowledge of Otsuka’s ’419 patent, as evidenced by Hetero’s September 11, 2019, Notice Letter.

118. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Hetero has infringed one or more claims of the ’419 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213669, seeking approval to commercially manufacture, use, import, offer to sell or sell Hetero’s generic products before the expiration date of the ’419 patent.

119. Upon information and belief, if ANDA No. 213669 is approved, Hetero will infringe one or more claims of the ’419 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Hetero’s generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213669 shall be no earlier than the expiration of the ’419 patent and any additional periods of exclusivity.

120. Upon information and belief, Hetero’s actions relating to Hetero’s ANDA No. 213669 complained of herein were done by and for the benefit of Hetero.

121. Plaintiffs will be irreparably harmed by Hetero’s infringing activities unless this

Court enjoins those activities.

122. Plaintiffs do not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Hetero has infringed at least one claim of each of the patents in suit through Hetero's submission of ANDA No. 213669 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Hetero's generic products in the United States before the expiration of the patents in suit;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Hetero's making, using, offering to sell, selling or importing of Hetero's generic products before the expiration of the patents in suit will infringe, actively induce infringement and/or contribute to the infringement of the patents in suit under 35 U.S.C. § 271(a), (b) and/or (c);

C. The issuance of an order that the effective date of any FDA approval of Hetero's generic products shall be no earlier than the expiration date of the patents in suit and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and/or permanent injunction, enjoining Hetero and all persons acting in concert with Hetero from commercially manufacturing, using, offering for sale or selling Hetero's generic products within the United States, or importing Hetero's generic products into the United States, until the expiration of the patents in suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining Hetero and all persons acting in concert with Hetero from seeking, obtaining or maintaining approval of the

ANDA until the expiration of the patents in suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

G. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

H. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

ASHBY & GEDDES

/s/ Steven J. Balick

Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-1888
sbalick@ashbygeddes.com
amayo@ashbygeddes.com

Attorneys for Plaintiffs Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S

Of Counsel:

James B. Monroe
Denise Main
Erin M. Sommers
Tyler B. Latcham
C. Collette Corser
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4431
(202) 408-4000

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