UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S, Plaintiffs, v. HETERO USA, INC., HETERO DRUGS, LTD., HETERO LABS, LTD., UNIT-V HETERO LABS, LTD. and HONOUR LAB LTD., Defendants	Civ. Action No. 19-cv-1954-LPS

DEFENDANTS HETERO USA, INC., HETERO DRUGS, LTD., HETERO LABS, LTD., UNIT-V HETERO LABS, LTD. AND HONOUR LAB LTD.'S ANSWER TO COMPLAINT

Defendants Hetero USA, Inc., Hetero Drugs, Ltd., Hetero Labs, Ltd. Unit-V and Hetero Labs, Ltd. (collectively, "Hetero") and Defendant Honour Lab Ltd. ("Honour")(collectively, "Defendants"), by its counsel, hereby respond to the allegations set forth in the Plaintiffs, Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S's ("Lundbeck") (collectively, "Plaintiffs"), Complaint for patent infringement against Defendants under 35 U.S.C. § 271(e)(2). This response is based on Defendants' current knowledge as to their own activities, and on information and belief as to the activities of others. If not specifically admitted herein, the allegations of the Complaint are denied.

1. Hetero admits that this action purports to arise under the United States, Patent Laws, Title 35, United States Code. Hetero further admits that Plaintiffs purport to seek relief from alleged 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"). Hetero admits that it filed ANDA No. 213669 with the FDA for approval to sell its ANDA product, as a generic version of Otsuka's Rexulti® drug product prior to the expiration of the patents-in-suit. Hetero denies the remaining allegations of paragraph 1.

THE PARTIES

2. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2 of the Complaint, and therefore denies them.

3. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3 of the Complaint, and therefore denies them.

4. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 4 of the Complaint, and therefore denies them.

5. Admitted.

6. Admitted.

7. Admitted.

8. Admitted.

9. Admitted.

10. Admitted.

11. Denied.

JURISDICTION AND VENUE

12. Paragraph 12 of the Complaint states a legal conclusion to which no response is required. Hetero will not contest subject matter jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Hetero in this case and solely as they apply to the proposed products described in ANDA No. 213669. Hetero denies any remaining allegations in this paragraph.

13. Paragraph 13 of the Complaint states a legal conclusion to which no response is

required. To the extent a response is required, Hetero will not contest personal jurisdiction for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

14. Paragraph 14 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero will not contest personal jurisdiction for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

15. Paragraph 15 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero will not contest personal jurisdiction for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

16. Paragraph 16 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that it filed ANDA No. 213669. Hetero denies any remaining allegations in this paragraph.

17. Paragraph 17 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero will not contest personal jurisdiction for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

18. Paragraph 18 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero will not contest personal jurisdiction for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

19. Paragraph 19 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero will not contest personal jurisdiction for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

20. Paragraph 20 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero will not contest personal jurisdiction for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

21. Paragraph 21 of the Complaint states a legal conclusion to which no response is

required. To the extent a response is required, Hetero will not contest personal jurisdiction for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

22. Denied. The Court does nor have personal jurisdiction over Honour, which has filed a motion to dismiss for lack of personal jurisdiction, lack of subject matter jurisdiction, and failure to state a claim upon which relief can be granted.

23. Paragraph 23 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Honour is one of many DMF holders for brexpiprazole. Honour denies any remaining allegations in this paragraph.

24. Paragraph 24 of the Complaint states a legal conclusion to which no response is required. Honour denies that this Court has personal jurisdiction over it. Contrary to Plaintiffs' allegation, Plaintiffs' first cited hyperlink at https://www.indiamart.com/heterolabs-limited/aboutus.html does not mention Honour and no association between Honour and Hetero can be ascertained from the link. Plaintiffs' second cited hyperlink at http://pharma.industry-report.net/honour-lab-ltd/ refers to a source to which neither Honour, nor Hetero supplied their corporate information. Also, contrary to Plaintiffs' allegation, the recited hyperlinks https://www.zaubacorp.com/company/HONOUR-LAB-LIMITED/U24233TG2011PLC077561 and https://www.zaubacorp.com/company/HETERO-LABS LIMITED/U24110TG1989PLC009723 do not contain any overlapping names to support Plaintiffs' allegation that they "share one or more corporate directors." Honour denies any remaining allegations in this paragraph.

25. Paragraph 25 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero will not contest personal jurisdiction for the limited purpose of this action only. Hetero denies and it and Honour hold themselves out as a unitary entity. Hetero denies any remaining allegations in this paragraph. Honour denies any remaining

allegations in this paragraph.

26. Paragraph 26 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that it filed ANDA No. 213669. Hetero will not contest personal jurisdiction for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

27. Paragraph 27 of the Complaint states a legal conclusion to which no response is required. Hetero admits that it filed ANDA No. 213669 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Hetero is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

28. Paragraph 28 of the Complaint states a legal conclusion to which no response is required. Hetero will not contest personal jurisdiction or venue for the limited purpose of this action only.

29. Paragraph 29 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero will not contest venue for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

30. Paragraph 30 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero will not contest venue for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

31. Paragraph 31 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero will not contest venue for the limited purpose of this action only. Hetero denies any remaining allegations in this paragraph.

FACTUAL BACKGROUND

The NDA

32. Admitted.

33. Hetero is without information sufficient to admit or deny the allegations in this paragraph and therefore denies the allegations.

34. Denied.

The Patents-In-Suit

35. Hetero admits that Plaintiffs purport that a true and correct copy of the ’362 patent is attached to the Complaint as Exhibit A. Hetero further admits that the ’362 patent is entitled “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders” and on its face indicates that it issued on February 15, 2011.

36. Hetero is without knowledge or information sufficient to admit or deny whether Otsuka owns the rights to the ’362 patent and/or whether Otsuka is an assignee of the ’362 patent. Hetero admits that the ’362 patent is assigned on its face to Otsuka.

37. Paragraph 37 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero is without knowledge or information sufficient to admit or deny whether the ’362 patent is properly a subject to terminal disclaimer. Hetero admits that Plaintiffs purport that a true and correct copy of the terminal disclaimer is attached to the Complaint as Exhibit B.

38. Hetero is without knowledge or information sufficient to admit or deny whether Otsuka’s calculations of the ’362 patent expiration date is accurate. Hetero admits that Plaintiffs purport that a true and correct copy of Otsuka’s submission for patent term extension is attached to the Complaint as Exhibit C.

39. Paragraph 39 of the Complaint states a legal conclusion to which no response is

required. To the extent a response is required, Hetero admits that the ’362 patent is listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations under Rexulti®.

40. Hetero admits that Plaintiffs purport that a true and correct copy of the ’840 patent is attached to the Complaint as Exhibit D. Hetero further admits that the ’840 patent is entitled “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders” and on its face indicates that it issued on January 8, 2013.

41. Hetero is without knowledge or information sufficient to admit or deny whether Otsuka owns the rights to the ’840 patent and/or whether Otsuka is an assignee of the ’840 patent. Hetero admits that the ’840 patent is assigned on its face to Otsuka.

42. Paragraph 42 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero is without knowledge or information sufficient to admit or deny whether the ’840 patent is properly a subject to terminal disclaimer.

43. Paragraph 43 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that the ’840 patent is listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations under Rexulti®.

44. Hetero admits that Plaintiffs purport that a true and correct copy of the ’109 patent is attached to the Complaint as Exhibit E. Hetero further admits that the ’109 patent is entitled “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders” and on its face indicates that it issued on December 31, 2013.

45. Hetero is without knowledge or information sufficient to admit or deny whether Otsuka owns the rights to the ’109 patent and/or whether Otsuka is an assignee of the ’109 patent. Hetero admits that the ’109 patent is assigned on its face to Otsuka.

46. Paragraph 46 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero is without knowledge or information sufficient

to admit or deny whether the ’109 patent is properly a subject to terminal disclaimer.

47. Paragraph 47 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that the ’109 patent is listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations under Rexulti®.

48. Hetero admits that Plaintiffs purport that a true and correct copy of the ’637 patent is attached to the Complaint as Exhibit E. Hetero further admits that the ’637 patent is entitled “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders” and on its face indicates that it issued on December 31, 2013.

49. Hetero is without knowledge or information sufficient to admit or deny whether Otsuka owns the rights to the ’637 patent and/or whether Otsuka is an assignee of the ’637 patent. Hetero admits that the ’637 patent is assigned on its face to Otsuka.

50. Paragraph 50 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero is without knowledge or information sufficient to admit or deny whether the ’637 patent is properly a subject to terminal disclaimer.

51. Paragraph 51 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that the ’637 patent is listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations under Rexulti®.

52. Hetero admits that Plaintiffs purport that a true and correct copy of the ’419 patent is attached to the Complaint as Exhibit G. Hetero further admits that the ’419 patent is entitled “Tablet comprising 7-[4-(4-benzo[b]thiopen-4-yl-piperazin-1-yl)butoxy]-1H-quinolin-2-one or a salt thereof.”

53. Hetero is without knowledge or information sufficient to admit or deny whether Otsuka owns the rights to the ’419 patent and/or whether Otsuka is an assignee of the ’419 patent. Hetero admits that the ’419 patent is assigned on its face to Otsuka.

54. Paragraph 54 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero is without knowledge or information sufficient to admit or deny whether the '419 patent expires on the indicated date.

55. Paragraph 55 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that the '419 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations under Rexulti®.

The ANDA

56. Hetero admits that it filed ANDA No. 213669 with the FDA for approval of the matters therein.

57. Hetero admits that it filed patent certifications pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the CFR in support of its Abbreviated New Drug Application ("ANDA"). Hetero denies any remaining allegations in this paragraph.

58. Hetero is without knowledge or information sufficient to admit or deny whether Otsuka has received a letter sent by Hetero. Hetero admits that on September 11, 2019, it sent a Notice Letter to Otsuka pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 and filed patent certifications pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the CFR in support of its Abbreviated New Drug Application ("ANDA"). Hetero denies any remaining allegations in this paragraph.

59. Paragraph 59 of the Complaint states a legal conclusion to which no response is required.

COUNT I

(INFRINGEMENT OF THE '362 PATENT)

60. Hetero incorporates by reference all of the answers in prior paragraphs.

61. Paragraph 61 of the Complaint states a legal conclusion to which no response is

required. To the extent a response is required, Hetero admits that it filed ANDA No. 213669 with the FDA for approval of the matters therein.

62. Hetero admits that it filed patent certifications pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the CFR in support of its Abbreviated New Drug Application ("ANDA"). Hetero denies any remaining allegations in this paragraph.

63. Paragraph 63 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that it filed ANDA No. 213669 with the FDA for approval of the matters therein.

64. Paragraph 64 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, submission of an ANDA to the FDA is merely a technical act of infringement and does not carry with it any implications of willful infringement.

65. Paragraph 65 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, submission of an ANDA to the FDA is merely a technical act of infringement and does not carry with it any implications of direct or indirect infringement.

66. Hetero admits that it filed ANDA No. 213669 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Hetero is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

67. Paragraph 67 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, submission of an ANDA to the FDA is merely a technical act of infringement and does not carry with it any implications of direct or indirect infringement.

68. Hetero is without knowledge or information sufficient to form a belief as to the truth

of the allegations of paragraph 68 of the Complaint, and therefore denies them.

69. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 69 of the Complaint, and therefore denies them.

70. Denied.

COUNT II

(INFRINGEMENT OF THE '840 PATENT)

71. Hetero incorporates by reference all of the answers in prior paragraphs.

72. Paragraph 72 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that it filed ANDA No. 213669 with the FDA for approval of the matters therein.

73. Hetero admits that it filed patent certifications pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the CFR in support of its Abbreviated New Drug Application ("ANDA"). Hetero denies any remaining allegations in this paragraph.

74. Paragraph 74 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that it filed ANDA No. 213669 with the FDA for approval of the matters therein.

75. Paragraph 75 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, submission of an ANDA to the FDA is merely a technical act of infringement and does not carry with it any implications of willful infringement.

76. Paragraph 76 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, submission of an ANDA to the FDA is merely a technical act of infringement and does not carry with it any implications of direct or indirect infringement.

77. Hetero admits that it filed ANDA No. 213669 with the FDA, seeking regulatory

approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Hetero is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

78. Hetero admits that it filed ANDA No. 213669 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Hetero is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

79. Hetero admits that it filed ANDA No. 213669 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Hetero is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

80. Hetero admits that it filed ANDA No. 213669 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Hetero is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

81. Hetero admits that it filed ANDA No. 213669 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Hetero is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

82. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 82 of the Complaint, and therefore denies them.

83. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 83 of the Complaint, and therefore denies them.

84. Denied.

COUNT III

(INFRINGEMENT OF THE '109 PATENT)

85. Hetero incorporates by reference all of the answers in prior paragraphs.

86. Hetero admits that it filed ANDA No. 213669 with the FDA for approval of the matters therein.

87. Hetero admits that it filed patent certifications pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the CFR in support of its Abbreviated New Drug Application ("ANDA"). Hetero denies any remaining allegations in this paragraph.

88. Paragraph 88 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that it filed ANDA No. 213669 with the FDA for approval of the matters therein.

89. Paragraph 89 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, submission of an ANDA to the FDA is merely a technical act of infringement and does not carry with it any implications of willful infringement.

90. Paragraph 90 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, submission of an ANDA to the FDA is merely a technical act of infringement and does not carry with it any implications of direct or indirect infringement.

91. Hetero admits that it filed ANDA No. 213669 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Hetero is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

92. Hetero admits that it filed ANDA No. 213669 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware.

Hetero is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

93. Hetero admits that it filed ANDA No. 213669 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Hetero is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

94. Hetero admits that it filed ANDA No. 213669 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Hetero is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

95. Hetero admits that it filed ANDA No. 213669 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Hetero is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

96. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 96 of the Complaint, and therefore denies them.

97. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 97 of the Complaint, and therefore denies them.

98. Denied.

COUNT IV

(INFRINGEMENT OF THE ’637 PATENT)

99. Hetero incorporates by reference all of the answers in prior paragraphs.

100. Hetero admits that it filed ANDA No. 213669 with the FDA for approval of the matters therein.

101. Hetero admits that it filed patent certifications pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the CFR in support of its Abbreviated New Drug Application ("ANDA"). Hetero denies any remaining allegations in this paragraph.

102. Paragraph 102 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that it filed ANDA No. 213669 with the FDA for approval of the matters therein.

103. Paragraph 103 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, submission of an ANDA to the FDA is merely a technical act of infringement and does not carry with it any implications of willful infringement.

104. Paragraph 104 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, submission of an ANDA to the FDA is merely a technical act of infringement and does not carry with it any implications of direct or indirect infringement.

105. Hetero admits that it filed ANDA No. 213669 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Hetero is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

106. Hetero admits that it filed ANDA No. 213669 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Hetero is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

107. Hetero admits that it filed ANDA No. 213669 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Hetero is without information sufficient to admit or deny the remaining allegations in this paragraph

and therefore denies the allegations.

108. Hetero admits that it filed ANDA No. 213669 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Hetero is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

109. Hetero admits that it filed ANDA No. 213669 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Hetero is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

110. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 110 of the Complaint, and therefore denies them.

111. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 111 of the Complaint, and therefore denies them.

112. Denied.

COUNT V

(INFRINGEMENT OF THE '419 PATENT)

113. Hetero incorporates by reference all of the answers in prior paragraphs.

114. Hetero admits that it filed ANDA No. 213669 with the FDA for approval of the matters therein.

115. Hetero admits that it filed patent certifications pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the CFR in support of its Abbreviated New Drug Application ("ANDA"). Hetero denies any remaining allegations in this paragraph.

116. Paragraph 116 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero admits that it filed ANDA No. 213669 with

the FDA for approval of the matters therein.

117. Paragraph 117 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, submission of an ANDA to the FDA is merely a technical act of infringement and does not carry with it any implications of willful infringement.

118. Paragraph 118 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, submission of an ANDA to the FDA is merely a technical act of infringement and does not carry with it any implications of direct or indirect infringement.

119. Hetero admits that it filed ANDA No. 213669 with the FDA, seeking regulatory approval to make and sell brexpiprazole tablets throughout the United States, including Delaware. Hetero is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

120. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 120 of the Complaint, and therefore denies them.

121. Hetero is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 121 of the Complaint, and therefore denies them.

122. Denied.

REQUESTED RELIEF

Hetero denies that Otsuka is entitled to any of the relief sought in its Prayer for Relief, including the relief sought in Paragraphs (A) through (H) on pages 20-21 of the Complaint.

AFFIRMATIVE DEFENSES

An allegation of any defense below is not an admission that Hetero bears the burden of proof or persuasion on any claim or issue.

First Affirmative Defense – Non-Infringement of the Claims of Patents-in-Suit

Hetero has not infringed, is not infringing, will not infringe, will not induce to infringe, and will not contribute to infringement of, literally or under the doctrine of equivalents, any valid and enforceable claims of the patents-in-suit.

Second Affirmative Defense – Invalidity of the Claims of Patents-in-Suit

The claims of the patents-in-suit are invalid and/or unenforceable for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation one or more of 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or for double patenting.

Third Affirmative Defense – Collateral Estoppel

Otsuka's claims are barred, in whole or in part, by the doctrine of collateral estoppel.

Fourth Affirmative Defense – Failure to State a Claim

Otsuka's Complaint fails to state a claim upon which relief can be granted.

RESERVATION OF ADDITIONAL DEFENSES

Hetero reserves the right to assert such other defenses and damages, if such defenses or and damages are discovered during the course of this litigation.

PRAYER FOR RELIEF

WHEREFORE, Hetero respectfully prays that this Court enter judgment in Hetero's favor and grant the following relief:

A. Dismiss Otsuka's Complaint with prejudice and deny each and every prayer for relief contained therein;

B. A declaration that Hetero does not infringe the claims of the patents-in-suit;

C. A declaration that the claims of the patents-in-suit are invalid;

D. Assess the costs of this action against Otsuka;

E. A declaration that this is an exceptional case within the meaning of 35 U.S.C. § 285,

and that Hetero is entitled to recover its reasonable attorney fees and costs upon prevailing in this action;

F. That the effective date of any FDA approval of Hetero's ANDA product shall not be stayed thirty months from the date of the Notice Letter, in accordance with 21 U.S.C. § 355(j)(5)(B)(iii);

G. An award to Hetero of such further and other relief as this Court deems necessary, just, and proper.

Date: January 27, 2020

Respectfully submitted,

MORRIS JAMES, LLP

/s/ Kenneth Dorsney
Kenneth L. Dorsney (#3726)
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801-1494
(302) 888-6855
kdorsney@morrisjames.com

Counsel for Defendants Hetero USA, Inc., Hetero Drugs, Ltd., Hetero Labs, Ltd. Unit-V, Hetero Labs, Ltd. and Honour Lab. Ltd.

Of Counsel:

Dmitry V. Shelhoff
Edward D. Pergament
PERGAMENT & CEPEDA LLP
89 Headquarters Plaza
North Tower, 14th Floor
Morristown, NJ 07960
(973) 998-7722
dshelhoff@pergamentcepeda.com
epergament@pergamentcepeda.com