IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOFFMANN-LA ROCHE, INC., CHUGAI PHARMACEUTICAL CO. LTD., AND GENENTECH, INC.	)	
Plaintiffs,	)	C.A. No. 20-cv-00394-RGA
v.	)	
FRESENIUS KABI USA, LLC,	)	
Defendant.	)	

FRESENIUS KABI USA, LLC'S ANSWER AND COUNTERCLAIMS

Defendant Fresenius Kabi USA, LLC ("Fresenius") hereby submits its Answer, Defenses, and Counterclaims ("Answer") to Plaintiffs Hoffman-La Roche, Inc. ("Roche"), Chugai Pharmaceutical Co. Ltd. ("Chugai"), and Genentech, Inc.'s ("Genentech," together with Roche and Chugai, "Plaintiffs") Complaint for Patent Infringement (D.I. 1) ("Complaint"). Fresenius Kabi Oncology Limited ("Fresenius Kabi Oncology") and Fresenius SE & Co. KGaA ("Fresenius KGaA") were dismissed from this case pursuant to a Stipulation and Order entered on May 20, 2020 (D.I. 10). This pleading is based upon Fresenius's knowledge as to its own activities, and upon information and belief as to the activities of others. To the extent any allegations in the Complaint are directed to Fresenius Kabi Oncology or Fresenius KGaA, no response is required from Fresenius. Pursuant to Federal Rule of Civil Procedure 8(b)(3), Fresenius denies every allegation not expressly admitted herein.

THE PARTIES

1. Fresenius lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 1 and therefore denies them.

2. Fresenius lacks knowledge or information sufficient to form a belief about the truth

of the allegations in Paragraph 2 and therefore denies them.

3. Fresenius lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 3 and therefore denies them.

4. Fresenius admits that it is a Delaware corporation with a principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

5. Fresenius Kabi Oncology was dismissed from this case pursuant to a Stipulation and Order entered on May 20, 2020 (D.I. 10). Because the allegations in Paragraph 5 are directed solely to Fresenius Kabi Oncology, no response is required.

6. Fresenius KGaA was dismissed from this case pursuant to a Stipulation and Order entered on May 20, 2020 (D.I. 10). Because the allegations in Paragraph 6 are directed solely to Fresenius KGaA, no response is required.

7. Fresenius KGaA and Fresenius Kabi Oncology were dismissed from this case pursuant to a Stipulation and Order entered on May 20, 2020 (D.I. 10). To the extent that the allegations in Paragraph 7 are directed to Fresenius KGaA and Fresenius Kabi Oncology, no response is required. Fresenius admits that its ultimate parent company is Fresenius KGaA.

8. Fresenius KGaA and Fresenius Kabi Oncology were dismissed from this case pursuant to a Stipulation and Order entered on May 20, 2020 (D.I. 10). To the extent that the allegations in Paragraph 8 are directed to Fresenius KGaA and Fresenius Kabi Oncology, no response is required. To the extent a response is required, denied.

9. Fresenius admits that it manufactures and distributes generic pharmaceutical products for sale in the United States. Otherwise denied.

NATURE OF THE ACTION

10. Paragraph 10 states a legal conclusion to which no response is required. To the

extent a response is required, Fresenius admits that Plaintiffs purport to state claims arising under the patent laws of the United States, Title 35, United States Code §§ 100, *et seq.*, and allege infringement of U.S. Patent Nos. 9,126,931 ("the '931 patent"), 9,440,922 ("the '922 patent"), 9,365,514 ("the '514 patent"), and 10,350,214 ("the '214 patent") (collectively, "the patents-in-suit"). Otherwise denied.

11. Fresenius admits that the ALECENSA® Label states that the "active ingredient" in ALECENSA® is "alectinib." Fresenius admits that the ALECENSA® Label states, "Alectinib is described chemically as 9-ethyl-6, 6-dimethyl-8-[4-(morpholin-4-yl)piperidin-1-yl]-11-oxo-6,11-dihydro-5*H*-benzo[*b*]carbazole-3-carbonitrile hydrochloride." Fresenius admits that the ALECENSA® Label further states that the "molecular formula for alectinib is $C_{30}H_{34}N_4O_2 \cdot HCl$." Fresenius admits that the ALECENSA® Label states the "molecular weight is 482.62 g/mol (free base form) and 519.08 g/mol (hydrochloride salt)." Fresenius lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in Paragraph 11 and therefore denies them.

12. Upon information and belief, Fresenius admits that Roche is listed as the holder of New Drug Application ("NDA") No. 208434 for ALECENSA® (alectinib) capsules, 150 mg for oral use, which was approved by the FDA for the treatment of patients with anaplastic lymphoma kinase ("ALK")-positive metastatic non-small cell lung cancer ("NSCLC") who have progressed on or are intolerant to crizotinib (Xalkori®). Fresenius lacks knowledge or information sufficient to form a belief about the truth of any remaining allegations in Paragraph 12 and therefore denies them.

13. Fresenius admits that the '931, '922, and '514 patents are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the

"Orange Book"). Fresenius lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 13 and therefore denies them.

14. Fresenius admits that it filed Abbreviated New Drug Application ("ANDA") No. 213166 ("Fresenius's ANDA") with the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FFDCA") to obtain approval for Alectinib Capsules, 150 mg ("Fresenius's ANDA Product") in the United States. Otherwise denied.

15. Fresenius Kabi Oncology was dismissed from this case pursuant to a Stipulation and Order entered on May 20, 2020 (D.I. 10). Because the allegations in Paragraph 15 are directed solely to Fresenius Kabi Oncology, no response is required.

16. Denied.

17. Denied.

18. Fresenius admits that it included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that, in its opinion and to the best of its knowledge, the '931, '514, and '922 patents are invalid, unenforceable, and/or will not be infringed by Fresenius's ANDA Product. Otherwise denied.

19. Fresenius admits that it sent a letter to Plaintiffs, dated February 5, 2020, ("Notice Letter") notifying Plaintiffs that Fresenius had submitted its ANDA to the FDA and that included therein was a Paragraph IV Certification as to the '931, '922, and '514 patents. Fresenius admits that it enclosed with the Notice Letter a statement of factual and legal bases as to why the '931, '922, and '514 patents are invalid, unenforceable, and/or will not be infringed by Fresenius's ANDA Product ("Detailed Statement"). Fresenius admits that, on information and belief, copies of the Notice Letter were delivered to each of Roche, Chugai, and Genentech between February 6, 2020 and February 7, 2020.

20. The Detailed Statement speaks for itself. Otherwise denied.

21. Fresenius admits that this action was filed on March 19, 2020 and that, on information and belief, copies of the Notice Letter were delivered to each of Roche, Chugai, and Genentech between February 6, 2020 and February 7, 2020.

22. Denied.

23. Denied.

JURISDICTION

24. Paragraph 24 states a legal conclusion to which no response is required. To the extent a response is required, Fresenius does not contest that, to the extent Plaintiffs have standing to assert claims of infringement of the patents-in-suit, this Court has subject matter jurisdiction over Plaintiffs' allegations arising from the filing of ANDA No. 213166. Otherwise denied.

25. Paragraph 25 states a legal conclusion to which no response is required. To the extent a response is required, Fresenius does not contest personal jurisdiction solely for the limited purposes of this particular action. Fresenius admits that it is organized under the laws of the State of Delaware and is registered to conduct business within the State of Delaware. Fresenius admits that it maintains, as a registered agent for service of process, Corporation Service Company, with an address at 251 Little Falls Drive, Wilmington, New Castle, Delaware 19808. Otherwise denied.

26. Fresenius Kabi Oncology was dismissed from this case pursuant to a Stipulation and Order entered on May 20, 2020 (D.I. 10). Because all allegations of Paragraph 26 are directed to Fresenius Kabi Oncology, no response is required.

27. Fresenius KGaA was dismissed from this case pursuant to a Stipulation and Order entered on May 20, 2020 (D.I. 10). Because all allegations of Paragraph 27 are directed to Fresenius KGaA and Fresenius Kabi Oncology, no response is required.

28. Paragraph 28 states a legal conclusion to which no response is required. To the extent a response is required, Fresenius does not contest personal jurisdiction solely for the limited purposes of this particular action, and states that Fresenius Kabi Oncology and Fresenius KGaA were dismissed from this case pursuant to a Stipulation and Order entered on May 20, 2020 (D.I. 10). Otherwise denied.

29. Fresenius KGaA and Fresenius Kabi Oncology Limited were dismissed from this case pursuant to a Stipulation and Order entered on May 20, 2020 (D.I. 10). To the extent the allegations of Paragraph 29 are directed to Fresenius KGaA and Fresenius Kabi Oncology Limited, no response is required. Fresenius admits that it manufactures and sells generic pharmaceutical products throughout the United States. Otherwise denied.

30. Fresenius admits that it filed ANDA No. 213166 with the FDA. Otherwise denied.

31. Denied.

32. Paragraph 32 states a legal conclusion to which no response is required. To the extent a response is required, Fresenius admits that, upon information and belief, Plaintiff Genentech is a Delaware corporation. Otherwise denied.

33. Denied.

34. Paragraph 34 states a legal conclusion to which no response is required. To the extent a response is required, Fresenius does not contest personal jurisdiction solely for the limited purposes of this particular action, and states that Fresenius Kabi Oncology and Fresenius KGaA were dismissed from this case pursuant to a Stipulation and Order entered on May 20, 2020 (D.I. 10). Otherwise denied.

35. Paragraph 35 states a legal conclusion to which no response is required. To the extent a response is required, Fresenius does not contest personal jurisdiction solely for the limited

purposes of this particular action, and states that Fresenius Kabi Oncology and Fresenius KGaA were dismissed from this case pursuant to a Stipulation and Order entered on May 20, 2020 (D.I. 10). Otherwise denied.

36. Paragraph 36 states a legal conclusion to which no response is required. To the extent a response is required, Fresenius does not contest personal jurisdiction solely for the limited purposes of this particular action, and states that Fresenius Kabi Oncology and Fresenius KGaA were dismissed from this case pursuant to a Stipulation and Order entered on May 20, 2020 (D.I. 10). Fresenius admits that it has asserted claims and counterclaims in prior actions in this judicial district. Otherwise denied.

VENUE

37. Paragraph 37 states a legal conclusion to which no response is required. To the extent a response is required, Fresenius does not contest venue solely for the limited purposes of this particular action, and states that Fresenius Kabi Oncology and Fresenius KGaA were dismissed from this case pursuant to a Stipulation and Order entered on May 20, 2020 (D.I. 10). Otherwise denied.

THE PATENTS-IN-SUIT

(U.S. PATENT NO. 9,126,931)

38. Fresenius incorporates by reference its responses to Paragraphs 1-37 as if fully set forth herein.

39. To the extent that Paragraph 39 states legal conclusions, no response is required. Fresenius admits that the ’931 patent is titled “Tetracyclic Compound” and states on its face that it issued on September 8, 2015. Fresenius admits that Kazutomo Kinoshita, Kohsuke Asoh, Noriyuki Furuichi, Toshiya Ito, Hatsuo Kawada, Nobuya Ishii, Hiroshi Sakamoto, WooSang

Hong, MinJeong Park, Yoshiyuki Ono, Yasuharu Kato, Kenji Morikami, Takashi Emura, and Nobuhiro Oikawa are listed as inventors on the face of the '931 patent. Fresenius admits that what appears to be a copy of the '931 patent is attached to the Complaint as Exhibit 1. Fresenius lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 39 and therefore denies them.

40. To the extent that Paragraph 40 states legal conclusions, no response is required. To the extent an answer is required, Fresenius admits that claim 15 of the '931 patent states, "[a] compound or salt or solvate as claimed in claim 1 of 9-ethyl-6,6-dimethyl-8-(4-morpholin-4-yl-piperidin-1-yl)-11-oxo-6,11-dihydro-5H-benzo[b]carbazole-3-carbonitrile." Otherwise denied.

(U.S. PATENT NO. 9,440,922)

41. Fresenius incorporates by reference its responses to Paragraphs 1-40 as if fully set forth herein.

42. To the extent that Paragraph 42 states legal conclusions, no response is required. Fresenius admits that the '922 patent is titled "Tetracyclic Compound" and states on its face that it issued on September 13, 2016. Fresenius admits that Kazutomo Kinoshita, Kohsuke Asoh, Noriyuki Furuichi, Toshiya Ito, Hatsuo Kawada, Nobuya Ishii, Hiroshi Sakamoto, WooSang Hong, MinJeong Park, Yoshiyuki Ono, Yasuharu Kato, Kenji Morikami, Takashi Emura, and Nobuhiro Oikawaare are listed as inventors on the face of the '922 patent. Fresenius admits that what appears to be a copy of the '922 patent is attached to the Complaint as Exhibit 2. Fresenius lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 42 and therefore denies them.

43. To the extent that Paragraph 43 states legal conclusions, no response is required. To the extent an answer is required, Fresenius admits that claim 20 of the '922 patent states, "[t]he

pharmaceutical of claim 1, wherein the compound represented by Formula (I) is 9-ethyl-6,6-dimethyl-8-(4-morpholin-4-yl-piperidin-1-yl)-11-oxo-6,11-dihydro-5H-benzo[b]carbazole-3-carbonitrile," and that claim 8 of the '922 patent states "[t]he pharmaceutical of claim 7, wherein the cancer is selected from the group consisting of lung cancer, anaplastic large cell lymphoma, inflammatory myofibroblastic tumor, esophageal cancer, and neuroblastoma." Otherwise denied.

(U.S. PATENT NO. 9,365,514)

44. Fresenius incorporates by reference its responses to Paragraphs 1-43 as if fully set forth herein.

45. To the extent that Paragraph 45 states legal conclusions, no response is required. To the extent a response is required, Fresenius admits that the '514 patent is titled "Composition Comprising Tetracyclic Compound" and states on its face that it issued on June 14, 2016. Fresenius admits that Kentaro Furumoto, Koji Shiraki, and Tomoaki Hirayama are listed as inventors on the face of the '514 patent. Fresenius admits that what appears to be a copy of the '514 patent is attached to the Complaint as Exhibit 3. Fresenius lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 45 and therefore denies them.

46. To the extent that Paragraph 46 states legal conclusions, no response is required. To the extent an answer is required, Fresenius admits that claim 1 of the '514 patent states "[a] composition comprising a substance which is 9-Ethyl-6,6-dimethyl-8-(4-morpholin-4-yl-piperidin-1-yl)-11-oxo-6,11-dihydro-5H-benzo[b]carbazole-3-carbonitrile or a salt thereof, a pharmaceutically acceptable carrier, and a dissolution aid, wherein the dissolution aid is sodium lauryl sulfate," that claim 2 of the '514 patent states "an orally administrable formulation comprising the composition described in claim 1," and that claim 3 of the '514 patent states, "the

composition according to claim 1, wherein the composition further comprises an organic polymer which is selected the group consisting of hydroxypropyl cellulose . . .” Otherwise denied.

(U.S. PATENT NO. 10,350,214)

47. Fresenius incorporates by reference its responses to Paragraphs 1-46 as if fully set forth herein.

48. To the extent that Paragraph 48 states legal conclusions, no response is required. To the extent a response is required, Fresenius admits that the ’214 patent is titled “Preparation Containing Tetracyclic Compound at High Dose,” and states on its face that it issued on June 16, 2016. Fresenius admits that Takashi Tomimatsu, Kensuke Okazaki, Yumi Ogawa, Takahiro Yamamura are listed as inventors on the face of the ’214 patent. Fresenius admits that what appears to be a copy of the ’214 patent is attached to the Complaint as Exhibit 4. Fresenius lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 48 and therefore denies them.

49. To the extent that Paragraph 49 states legal conclusions, no response is required. To the extent an answer is required, Fresenius admits that claim 1 of the ’214 patent states, “a pharmaceutical formulation comprising (i) a granule containing a compound represented by formula (I) or a salt thereof and (ii) carmellose calcium as a disintegrating agent, wherein the compound represented by formula (I) or a salt thereof is contained in an amount of 140 mg to 190 mg in terms of the free form per unit formulation.” Fresenius admits that claim 5 of the ’214 patent states, “[t]he formulation according to claim 1, wherein the granule contains a solubilizing agent therein.” Fresenius admits that claim 6 of the ’214 patent states, “the formulation according to claim 5, wherein the solubilizing agent is sodium lauryl sulfate.” Fresenius admits that claim 10 of the ’214 patent states, “the formulation according to claim 1, wherein the granule contains a

binder therein," and that claim 11 of the '214 patent states, "the formulation according to claim 10, wherein the binder is hydroxypropylcellulose." Otherwise denied.

COUNT I
(Alleged Infringement of the '931 Patent)

50. Fresenius incorporates by reference its responses to Paragraphs 1-49 as if fully set forth herein.

51. Fresenius admits that it filed its ANDA under § 505(j) of the FFDCA and included in its ANDA a Paragraph IV Certification concerning the '931 patent and any extensions thereof. Otherwise denied.

52. The Notice Letter speaks for itself. Otherwise denied.

53. To the extent paragraph 53 states legal conclusions, no response is required. To the extent a response is required, Fresenius admits that it was aware of the '931 patent at least as of December 11, 2019. Otherwise denied.

54. Fresenius admits that the ALECENSA® Label states, "ALECENSA (alectinib) is a kinase inhibitor for oral administration." Fresenius admits that the ALECENSA® Label states, "[a]lectinib is described chemically as 9-ethyl-6,6-dimethyl-8-[4-(morpholin-4-yl)piperidin-1-yl]-11-oxo-6,11-dihydro-5*H*-benzo[*b*]carbazole-3-carbonitrile hydrochloride," and "the molecular formula for alectinib is $C_{30}H_{34}N_4O_2 \cdot HCl$." Fresenius admits that the ALECENSA® Label states the "molecular weight is 482.62 g/mol (free base form) and 519.08 g/mol (hydrochloride salt)." Otherwise denied.

55. Paragraph 55 states a legal conclusion to which no response is required. To the extent a response is required, Fresenius admits that claim 15 of the '931 patent states, "a compound or salt or solvate as claimed in claim 1 of 9-ethyl-6, 6-dimethyl-8-[4-(morpholin-4-yl)piperidin-1-yl]-11-oxo-6,11-dihydro-5*H*-benzo[*b*]carbazole-3-carbonitrile." Otherwise denied.

56. Paragraph 56 states a legal conclusion to which no response is required. To the extent a response is required, Fresenius admits that claim 15 of the '931 patent states, "a compound or salt or solvate as claimed in claim 1 of 9-ethyl-6, 6-dimethyl-8-[4-(morpholin-4-yl)piperidin-1-yl]-11-oxo-6,11-dihydro-5*H*-benzo[*b*]carbazole-3-carbonitrile." Otherwise denied.

57. Admitted.

58. Denied.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

63. Denied.

64. Fresenius denies that Plaintiffs are entitled to the relief requested. Fresenius denies the remaining allegations in Paragraph 64.

65. Fresenius denies that Plaintiffs are entitled to the relief requested. Fresenius denies the remaining allegations in Paragraph 65.

66. Fresenius denies that Plaintiffs are entitled to the relief requested. Fresenius denies the remaining allegations in Paragraph 66.

67. Fresenius denies that Plaintiffs are entitled to the relief requested. Fresenius denies the remaining allegations in Paragraph 67.

68. Denied.

69. Denied.

70. Denied.

COUNT II
(Alleged Infringement of the '922 Patent)

71. Fresenius incorporates by reference its responses to Paragraphs 1-70 as if fully set forth herein.

72. Fresenius admits that it filed its ANDA under § 505(j) of the FFDCA and included in its ANDA a Paragraph IV Certification concerning the '922 patent and any extensions thereof. Otherwise denied.

73. The Notice Letter speaks for itself. Otherwise denied.

74. To the extent Paragraph 74 states legal conclusions, no response is required. To the extent a response is required, Fresenius admits that it was aware of the '922 patent at least as early as December 11, 2019. Otherwise denied.

75. Admitted.

76. Fresenius admits that the ALECENSA® Label states, "ALECENSA (alectinib) is a kinase inhibitor for oral administration." Fresenius admits that the ALECENSA® Label states, "[a]lectinib is described chemically as 9-ethyl-6,6-dimethyl-8-[4-(morpholin-4-yl)piperidin-1-yl]-11-oxo-6,11-dihydro-5H-benzo[b]carbazole-3-carbonitrile hydrochloride" and that "the molecular formula for alectinib is $C_{30}H_{34}N_4O_2 \cdot HCl$." Fresenius admits that the ALECENSA® Label states the "molecular weight is 482.62 g/mol (free base form) and 519.08 g/mol (hydrochloride salt)." Otherwise denied.

77. Fresenius admits that the ALECENSA® Label states, "ALECENSA is a kinase inhibitor indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test." Otherwise denied.

78. To the extent Paragraph 78 states legal conclusions, no response is required. To

the extent a response is required, Fresenius admits that claim 8 of the '922 patent states, "the pharmaceutical of claim 7, wherein the cancer is selected from the group consisting of lung cancer, anaplastic large cell lymphoma, inflammatory myofibroblastic tumor, esophageal cancer, and neuroblastoma." Fresenius admits that claim 20 of the '922 patent states, "the pharmaceutical of claim 1, wherein the compound represented by Formula (I) is 9-ethyl-6,6-dimethyl-8-(4-morpholin-4-yl-piperidin-1-yl)-11-dihydro-5H-benzo[b]carbazole-3-carbonitrile." Otherwise denied.

79. To the extent Paragraph 79 states legal conclusions, no response is required. To the extent a response is required, Fresenius states that it lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 79 and therefore denies them.

80. Admitted.

81. Denied.

82. Denied.

83. Denied.

84. Denied.

85. Denied.

86. Denied.

87. Fresenius denies that Plaintiffs are entitled to the relief requested. Fresenius denies the remaining allegations in Paragraph 87.

88. Fresenius denies that Plaintiffs are entitled to the relief requested. Fresenius denies the remaining allegations in Paragraph 88.

89. Fresenius denies that Plaintiffs are entitled to the relief requested. Fresenius denies the remaining allegations in Paragraph 89.

90. Fresenius denies that Plaintiffs are entitled to the relief requested. Fresenius denies the remaining allegations in Paragraph 90.

91. Denied.

92. Denied.

93. Denied.

COUNT III
(Alleged Infringement of the '514 Patent)

94. Fresenius incorporates by reference its responses to Paragraphs 1-93 as if fully set forth herein.

95. Fresenius admits that it filed its ANDA under § 505(j) of the FFDCA and included in its ANDA a Paragraph IV Certification concerning the '514 patent and any extensions thereof. Otherwise denied.

96. The Notice Letter speaks for itself. Otherwise denied.

97. To the extent Paragraph 97 states legal conclusions, no response is required. To the extent a response is required, Fresenius admits it was aware of the '514 patent at least as early as December 11, 2019. Otherwise denied.

98. Fresenius admits that the ALECENSA® Label states that ALECENSA (alectinib) "is supplied as hard capsules containing 150 mg of alectinib (equivalent to 161.33 mg alectinib HCl) and the following inactive ingredients: lactose monohydrate, hydroxypropylcellulose, sodium lauryl sulfate, magnesium stearate, and carboxymethylcellulose calcium." Fresenius lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 98 and therefore denies them.

99. Fresenius admits that the ALECENSA® Label states, "ALECENSA (alectinib) is a kinase inhibitor for oral administration." Fresenius admits that the ALECENSA® Label states,

"[a]lectinib is described chemically as 9-ethyl-6, 6-dimethyl-8-[4-(morpholin-4-yl)piperidin-1-yl]-11-oxo-6,11-dihydro-5*H*-benzo[*b*]carbazole-3-carbonitrile hydrochloride," and that "the molecular formula for alectinib is $C_{30}H_{34}N_4O_2 \cdot HCl$." Fresenius admits that the ALECENSA® Label states the "molecular weight is 482.62 g/mol (free base form) and 519.08 g/mol (hydrochloride salt)." Otherwise denied.

100. To the extent Paragraph 100 states a legal conclusion, no response is required. To the extent a response is required, Fresenius admits that claim 1 of the '514 patent states "a composition comprising a substance which is 9-Ethyl-6,6-dimethyl-8-(4-morpholin-4-yl-piperidin-1-yl)-11-oxo-6,11-dihydro-5H-benzo[b]carbazole-3-carbonitrile or a salt thereof, a pharmaceutically acceptable carrier, and a dissolution aid, wherein the dissolution aid is sodium lauryl sulfate." Fresenius admits that claim 3 of the '514 patent states "the composition according to claim 1, wherein the composition further comprises an organic polymer which is selected the group consisting of hydroxypropyl cellulose . . ." Otherwise denied.

101. Denied.

102. Admitted.

103. Denied.

104. Denied.

105. Denied.

106. Denied.

107. Denied.

108. Denied.

109. Fresenius denies that Plaintiffs are entitled to the relief requested. Fresenius denies the remaining allegations in Paragraph 109.

110. Fresenius denies that Plaintiffs are entitled to the relief requested. Fresenius denies the remaining allegations in Paragraph 110.

111. Fresenius denies that Plaintiffs are entitled to the relief requested. Fresenius denies the remaining allegations in Paragraph 111.

112. Fresenius denies that Plaintiffs are entitled to the relief requested. Fresenius denies the remaining allegations in Paragraph 112.

113. Denied.

114. Denied.

115. Denied.

COUNT IV
(Alleged Infringement of the '214 Patent)

116. Fresenius incorporates by reference its responses to Paragraphs 1-115 as if fully set forth herein.

117. Denied.

118. Fresenius admits that the '214 patent is currently listed in the Orange Book for ALCENSA®. Fresenius lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 118 and therefore denies them.

119. Fresenius admits that the ALECENSA® Label states that ALECENSA (alectinib) "is supplied as hard capsules containing 150 mg of alectinib (equivalent to 161.33 mg alectinib HCl) and the following inactive ingredients: lactose monohydrate, hydroxypropylcellulose, sodium lauryl sulfate, magnesium stearate, and carboxymethylcellulose calcium." Fresenius lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 119 and therefore denies them.

120. Fresenius admits that the ALECENSA® Label states, "ALECENSA (alectinib) is a

kinase inhibitor for oral administration." Fresenius admits that the ALECENSA® Label states, "[a]lectinib is described chemically as 9-ethyl-6, 6-dimethyl-8-[4-(morpholin-4-yl)piperidin-1-yl]-11-oxo-6,11-dihydro-5*H*-benzo[*b*]carbazole-3-carbonitrile hydrochloride," and that "the molecular formula for alectinib is $C_{30}H_{34}N_4O_2 \cdot HCl$." Fresenius admits that the ALECENSA® Label states the "molecular weight is 482.62 g/mol (free base form) and 519.08 g/mol (hydrochloride salt)." Otherwise denied.

121. To the extent Paragraph 121 states a legal conclusion, no response is required. To the extent a response is required, Fresenius admits that claims 1 and 15 of the '214 patent recite "carmellose calcium" and depict the chemical structure of alectinib. Fresenius admits that claims 6, 7, and 21 of the '214 patent recite "sodium lauryl sulfate." Fresenius admits that claims 11 and 24 recite "hydroxypropylcellulose." Otherwise denied.

122. Denied.

123. Denied.

124. Denied.

125. Denied.

126. Denied.

127. Denied.

128. Denied.

129. Fresenius denies that Plaintiffs are entitled to the relief requested. Fresenius denies the remaining allegations in Paragraph 129.

130. Fresenius denies that Plaintiffs are entitled to the relief requested. Fresenius denies the remaining allegations in Paragraph 130.

131. Fresenius denies that Plaintiffs are entitled to the relief requested. Fresenius denies

the remaining allegations in Paragraph 131.

132. Fresenius denies that Plaintiffs are entitled to the relief requested. Fresenius denies the remaining allegations in Paragraph 132.

133. Denied.

134. Denied.

135. Denied.

PRAYER FOR RELIEF

Fresenius denies each and every allegation in the Complaint not expressly admitted above. Fresenius denies that the Plaintiff is entitled to the judgment and relief prayed for in paragraphs A through I) of the Prayer for Relief.

AFFIRMATIVE DEFENSES

Without any admissions as to burden of proof, and expressly reserving its right to assert additional defenses, Fresenius states the following affirmative defenses:

FIRST AFFIRMATIVE DEFENSE
(Failure to state a claim)

Plaintiffs' Complaint fails to state a claim against Fresenius upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE
(Invalidity)

One or more claims of the patents-in-suit are invalid because they do not comply with one or more of the requirements for patentability set forth in 35 U.S.C. §§ 101, 102, 103, 112, et seq., and/or are invalid under the doctrines of anticipation-type or obviousness-type double patenting, and/or for any other judicially-created and/or non-statutory basis for invalidity or unenforceability.

THIRD AFFIRMATIVE DEFENSE
(Non-infringement)

The manufacture, use, offer to sell or sale in the United States, or importation into the United States, of Fresenius's ANDA Product would not infringe any valid and enforceable claim of the patents-in-suit.

FOURTH AFFIRMATIVE DEFENSE
(No Costs)

Plaintiffs are barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

FIFTH AFFIRMATIVE DEFENSE
(No Injunctive Relief)

Plaintiffs may not seek injunctive relief against Fresenius because Plaintiffs' alleged damages are not immediate or irreparable, and Plaintiffs therefore have an adequate remedy at law.

SIXTH AFFIRMATIVE DEFENSE
(No Willful Infringement)

Fresenius has not, does not, and/or will not willfully infringe any valid or enforceable claim of the patents-in-suit, and Plaintiffs are not entitled to enhanced damages.

SEVENTH AFFIRMATIVE DEFENSE
(Exceptional Case)

Fresenius is entitled to an award of its reasonable attorneys' fees to be assessed against Plaintiffs in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable, including without limitation, Fed. R. Civ. P. 11.

EIGHTH AFFIRMATIVE DEFENSE
(Reservation of Rights)

Fresenius specifically reserves the right to assert each and every other defense that may become evident during the course of discovery.

COUNTERCLAIMS

Defendant-Counterclaim Plaintiff Fresenius Kabi USA, LLC ("Fresenius"), for its counterclaims against Plaintiff-Counterclaim Defendants Hoffman-La Roche, Inc. ("Roche"), Chugai Pharmaceutical Co. Ltd. ("Chugai"), and Genentech, Inc. ("Genentech", together with Roche and Chugai, "Plaintiffs" or "Counterclaim Defendants"), alleges as follows:

NATURE OF THE ACTION

1. Counterclaim Plaintiff Fresenius repeats and incorporates by reference its responses and affirmative defenses to Paragraphs 1-135 and the Prayer for Relief of Counterclaim Defendants' Complaint as if fully set forth herein.

2. This is an action for a judgment declaring that the claims of U.S. Patent Nos. 9,126,931 ("the '931 patent"), 9,440,922 ("the '922 patent"), 9,365,514 ("the '514 patent"), and 10,350,214 ("the '214 patent") (collectively, "the patents-in-suit") are invalid and/or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, offer to sell or sale in the United States, or importation into the United States, of Alectinib Capsules, 150 mg, described in Abbreviated New Drug Application ("ANDA") No. 213166 ("Fresenius's ANDA Product").

THE PARTIES

3. Counterclaim Plaintiff Fresenius is a limited liability company organized and existing under the laws of Delaware, with its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

4. Counterclaim Defendant Roche avers that it is a corporation organized and existing under the laws of New Jersey, with its principal place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424, United States.

5. Counterclaim Defendant Chugai avers that it is a Japanese corporation with a

principal place of business address at 5-chome-5-1 Ukima, Kita-Ku, Tokyo 115-8543, Japan.

6. Counterclaim Defendant Genentech avers that it is a corporation organized under the laws of Delaware with a principal place of business at 1 DNA Way, San Francisco, California, 94080, United States.

JURISDICTION AND VENUE

7. These Counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201(a) and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

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

9. Counterclaim Defendants Roche, Chugai, and Genentech submitted to the personal jurisdiction of this Court by filing their Complaint in this action.

10. Venue is proper in this Judicial District under 28 U.S.C. § 1391(b) and (c).

FACTUAL BACKGROUND

11. According to the United States Food & Drug Administration ("FDA") publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations (the "Orange Book"), Roche holds approved New Drug Application ("NDA") No. 208434 for ALECENSA® (alectinib) capsules, 150 mg.

12. NDA holders are required to disclose to the FDA the patent numbers of patents claiming the drug or the method of using such drug for which the NDA is submitted. The FDA lists these patents in the Orange Book.

13. The '931 patent is entitled "Tetracyclic Compound" and states that it was issued on September 8, 2015.

14. The '922 patent is entitled "Tetracyclic Compound" and states that it was issued on

September 13, 2016.

15. The '514 patent is entitled "Composition Comprising Tetracyclic Compound" and states that it was issued on June 14, 2016.

16. The '214 patent is entitled "Preparation Containing Tetracyclic Compound at High Dose" and states that it was issued on July 16, 2019.

17. Each of the patents-in-suit is listed in the Orange Book with respect to ALECENSA® (alectinib) capsules, 150 mg.

18. Upon information and belief, Roche caused the patents-in-suit to be listed in the Orange Book as patents that claim ALECENSA® (alectinib) capsules, 150 mg., or methods of using ALECENSA® (alectinib) capsules, 150 mg.

19. Fresenius submitted to the FDA ANDA No. 213166 seeking approval to engage in the commercial manufacture, use or sale of Fresenius's ANDA Product. ANDA No. 213166 contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the patents-in-suit are invalid and/or will not be infringed by the manufacture, use or sale of Fresenius's ANDA Product.

20. On February 5, 2020, Fresenius sent a letter to each Counterclaim Defendant stating that it had submitted to the FDA ANDA No. 213166 seeking approval to engage in the commercial manufacture, use or sale of Fresenius's ANDA Product prior to the expiration of the patents-in-suit ("Notice Letter"). Fresenius's Notice Letter included a detailed statement of the factual and legal bases for Fresenius's opinion that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of Fresenius's ANDA Product ("Detailed Statement"). On information and belief, copies of the Notice Letter were delivered to each of Roche, Chugai, and Genentech between February 6, 2020 and February 7, 2020.

21. On March 19, 2020, Plaintiffs filed a Complaint against Fresenius, Fresenius Kabi Oncology Limited ("Fresenius Kabi Oncology") and Fresenius SE & Co. KGaA ("Fresenius KGaA") in this Court. Fresenius Kabi Oncology and Fresenius KGaA were dismissed from this case pursuant to a Stipulation and Order entered on May 20, 2020 (D.I. 10).

22. Counterclaim Defendants allege in their Complaint that Fresenius infringes certain claims of each of the patents-in-suit by virtue of having filed ANDA No. 213166, seeking approval to engage in the commercial manufacture, use or sale of Fresenius's ANDA Product prior to the expiration of the patents-in-suit. Chugai avers that it is the owner of each of the patents-in-suit. Copies of the patents-in-suit were attached as exhibits to Counterclaim Defendants' Complaint.

THE EXISTENCE OF AN ACTUAL CONTROVERSY

23. As a consequence of the patents-in-suit being listed in the Orange Book with respect to ALECENSA® (alectinib) capsules, 150 mg.; Fresenius's filing of ANDA No. 213166 with accompanying Paragraph IV Certification regarding the '931, '922, and '514 patents; Fresenius's serving of its Notice Letter on each Counterclaim Defendant; and the allegations of infringement of all patents-in-suit made against Fresenius by Counterclaim Defendants in their Complaint, there is an actual controversy between Fresenius and Counterclaim Defendants, redressable by judgment of this Court, as to the non-infringement and invalidity of the claims of the patents-in-suit.

FIRST COUNTERCLAIM
(Non-infringement of the '931 patent)

24. Fresenius repeats and incorporates by reference Paragraphs 1-23 of these Counterclaims as if fully set forth herein.

25. Fresenius incorporates by reference the contents of its Detailed Statement, which contains exemplary and nonlimiting explanations that the claims of the '931, '922, and '514 patents are invalid and not infringed.

26. Fresenius has not infringed and is not liable for infringement of the ’931 patent.

27. Fresenius’s manufacture, use, offer for sale, or sale in the United States or importation into the United States of its ANDA Product would not infringe any valid and enforceable claim of the ’931 patent, either literally or under the doctrine of equivalents.

28. Fresenius is entitled to a declaratory judgment that it has not infringed and is not liable for infringement of the ’931 patent, and that its manufacture, use, offer for sale, or sale in the United States or importation into the United States of its ANDA Product would not infringe any valid and enforceable claim of that patent, either literally or under the doctrine of equivalents.

29. Fresenius is entitled to an award of costs and expenses, including reasonable attorneys’ fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

SECOND COUNTERCLAIM
(Non-infringement of the ’922 patent)

30. Fresenius repeats and incorporates by reference Paragraphs 1-29 of these Counterclaims as if fully set forth herein.

31. Fresenius has not infringed and is not liable for infringement of the ’922 patent.

32. Fresenius’s manufacture, use, offer for sale, or sale in the United States or importation into the United States of its ANDA Product would not infringe any valid and enforceable claim of the ’922 patent, either literally or under the doctrine of equivalents.

33. Fresenius is entitled to a declaratory judgment that it has not infringed and is not liable for infringement of the ’922 patent, and that its manufacture, use, offer for sale, or sale in the United States or importation into the United States of its ANDA Product would not infringe any valid and enforceable claim of that patent, either literally or under the doctrine of equivalents.

34. Fresenius is entitled to an award of costs and expenses, including reasonable

attorneys' fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

THIRD COUNTERCLAIM
(Non-infringement of the '514 patent)

35. Fresenius repeats and incorporates by reference Paragraphs 1-34 of these Counterclaims as if fully set forth herein.

36. Fresenius has not infringed and is not liable for infringement of the '514 patent.

37. Fresenius's manufacture, use, offer for sale, or sale in the United States or importation into the United States of its ANDA Product would not infringe any valid and enforceable claim of the '514 patent, either literally or under the doctrine of equivalents.

38. Fresenius is entitled to a declaratory judgment that it has not infringed and is not liable for infringement of the '514 patent, and that its manufacture, use, offer for sale, or sale in the United States or importation into the United States of its ANDA Product would not infringe any valid and enforceable claim of that patent, either literally or under the doctrine of equivalents.

39. Fresenius is entitled to an award of costs and expenses, including reasonable attorneys' fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

FOURTH COUNTERCLAIM
(Non-Infringement of the '214 Patent)

40. Fresenius repeats and incorporates by reference Paragraphs 1-39 of these Counterclaims as if fully set forth herein.

41. Fresenius has not infringed and is not liable for infringement of the '214 patent.

42. Fresenius's manufacture, use, offer for sale, or sale in the United States or importation into the United States of its ANDA Product would not infringe any valid and enforceable claim of the '214 patent, either literally or under the doctrine of equivalents.

43. Fresenius is entitled to a declaratory judgment that it has not infringed and is not liable for infringement of the '214 patent, and that its manufacture, use, offer for sale, or sale in the United States or importation into the United States of its ANDA Product would not infringe any valid and enforceable claim of that patent, either literally or under the doctrine of equivalents.

44. Fresenius is entitled to an award of costs and expenses, including reasonable attorneys' fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

FIFTH COUNTERCLAIM
(Invalidity of the '931 Patent)

45. Fresenius repeats and incorporates by reference Paragraphs 1-44 of these Counterclaims as if fully set forth herein.

46. Each of the claims of the '931 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112., et seq. and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability and the rules, regulations and laws pertaining thereto.

47. For example, claims 1-4 and 15 of the '931 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of at least the following prior art:

- Adrian T. Boogaard et al., *Ring D Modifications of Ellipticine. Part 2. Chlorination of Ellipticine via its N-oxide and Synthesis and Selective Acetylation of 5,6,11-Trimethyl-5H-Benzo[b]Carbazole*, 50 TETRAHEDRON 4811 (1994)
- Anna V. Galkin et al., *Identification of NVP-TAE684, a potent, selective, and efficacious inhibitor of NPM-ALK*, 104 PNAS 270 (2007)
- Christian Asche et al., *Synthesis, Antitumour Activity and Structure-Activity Relationships of 5H-benzo[b]carbazoles*, 13 BIOORG. & MED. CHEM. 819 (2005)
- Hans-Joachim Knölker & Wolfgang Fröhner, *Transition Metal Complexes in Organic Synthesis, Part 38. First Total Synthesis of Carbazomycin G and H*, 38

TETRAHEDRON LETTERS 4051 (1997)

- Jeffrey Jie-Lou Liao, *Molecular Recognition of Protein Kinase Binding Pockets for Design and Potent and Selective Kinase Inhibitors*, 50 J. MED. CHEM. 409 (2007)
- Jérémie Vendôme et al., *Molecular Modeling of Wild-Type and D816V c-Kit Inhibition Based on ATP-competitive Binding of Ellipticine Derivatives to Tyrosine Kinases*, 48 J. MED. CHEM. 6194 (2005)
- Paul H. Bernardo et al., *Synthesis, Electrochemistry, and Bioactivity of the Cyanobacterial Calothrixins and Related Quinones*, 47 J. MED. CHEM. 4958 (2004)
- PCT Publication No. WO 2005/009389
- PCT Publication No. WO 2007/130468
- Robert P. Sheridan, *The Most Common Chemical Replacements in Drug-Like Compounds*, 42 J. CHEM. INF. COMPUT. SCI. 103 (2002)
- Rongshi Li et al., *Design and Synthesis of 5-aryl-pyridone-carboxamides as Inhibitors of Anaplastic Lymphoma Kinase*, 49 J. MED. CHEM. 1006 (2006)
- Rongshi Li & Stephan W. Morris, *Development of Anaplastic Lymphoma Kinase (ALK) Small-Molecule Inhibitors for Cancer Therapy*, 28 MED. RES. REV. 372 (2008)
- U.S. Patent Publication No. 2004/0072890

48. As another example, every claim of the ’931 patent is invalid under the judicially-created doctrines of anticipation-type double patenting and/or obviousness-type double patenting over the claims of the ’922 patent, either alone or in view of at least the prior art listed in Paragraph 47.

49. As a further example, every claim of the ’931 patent is invalid for lack of enablement and written description under 35 U.S.C. § 112, first paragraph because there is insufficient information in the specification and prosecution history to allow a person of skill in the art (“POSA”) to either (1) ascertain that the inventors actually possessed the full scope of the claimed subject matter at the time of filing; or (2) practice the full scope of the claimed subject

matter without undo experimentation.

50. As yet another example, every claim of the '931 patent is invalid as indefinite under 35 U.S.C. § 112, second paragraph because there is insufficient information in the specification and prosecution history to inform a POSA about the scope of the invention with reasonable certainty.

51. Fresenius is entitled to a declaratory judgment that each of the claims of the '931 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112., et seq. and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability and the rules, regulations, and laws pertaining thereto.

52. Fresenius is entitled to an award of costs and expenses, including reasonable attorneys' fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

SIXTH COUNTERCLAIM
(Invalidity of the '922 Patent)

53. Fresenius repeats and incorporates by reference Paragraphs 1-52 of these Counterclaims as if fully set forth herein.

54. Each of the claims of the '922 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112., et seq. and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability and the rules, regulations, and laws pertaining thereto.

55. For example, claims 1-8 and 20 of the '922 patent are invalid under 35 U.S.C. § 102 and/or § 103 in view of at least the prior art listed above in Paragraph 47.

56. As a further example, every claim of the '922 patent is invalid for lack of enablement and written description under 35 U.S.C. § 112, first paragraph because there is

insufficient information in the specification and prosecution history to allow a POSA to either (1) ascertain that the inventors actually possessed the full scope of the claimed subject matter at the time of filing; or (2) practice the full scope of the claimed subject matter without undo experimentation.

57. As yet another example, every claim of the '922 patent is invalid as indefinite under 35 U.S.C. § 112, second paragraph because there is insufficient information in the specification and prosecution history to inform a POSA about the scope of the invention with reasonable certainty.

58. Fresenius is entitled to a declaratory judgment that each of the claims of the '922 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112., et seq. and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability and the rules, regulations, and laws pertaining thereto.

59. Fresenius is entitled to an award of costs and expenses, including reasonable attorneys' fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

SEVENTH COUNTERCLAIM
(Invalidity of the '514 Patent)

60. Fresenius repeats and incorporates by reference Paragraphs 1-59 of these Counterclaims as if fully set forth herein.

61. Each of the claims of the '514 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112, et seq. and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability and the rules, regulations, and laws pertaining thereto.

62. For example, every claim of the '514 patent is invalid under 35 U.S.C. § 102 and/or

§ 103 in view of at least the prior art listed in Paragraph 47, as well as the following prior art:

- PCT Publication No. WO 2004/000279
- R. K. Chang et al., *Polymethacrylates in* HANDBOOK OF PHARMACEUTICAL EXCIPIENTS 525 (Raymond C. Rowe et al. eds., 6th ed. 2009)
- P. Plumb, *Sodium Lauryl Sulfate in* HANDBOOK OF PHARMACEUTICAL EXCIPIENTS 651 (Raymond C. Rowe et al. eds., 6th ed. 2009)

63. As a further example, every claim of the '514 patent is invalid under the judicially-created doctrine of obviousness-type double patenting over the claims of the '931 and/or '922 patents in view of at least the prior art listed in Paragraphs 47 and 62.

64. Fresenius is entitled to a declaratory judgment that each of the claims of the '514 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112, et seq. and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability and the rules, regulations, and laws pertaining thereto.

65. Fresenius is entitled to an award of costs and expenses, including reasonable attorneys' fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

EIGHTH COUNTERCLAIM
(Invalidity of the '214 Patent)

66. Fresenius repeats and hereby incorporates by reference Paragraphs 1-65 of these Counterclaims as if fully set forth herein.

67. Each of the claims of the '214 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112., et seq. and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability and the rules, regulations, and laws pertaining thereto.

68. For example, every claim of the '214 patent is invalid under 35 U.S.C. § 102 and/or

§ 103 in view of at least the following prior art:

- Akira Inoue et al., *One Year Follow-up of a Phase I/II Study of a Highly Selective ALK Inhibitor CH5424802/RO5424802 in ALK-Rearranged Advanced Non-small Cell Lung Cancer (NSCLC)*, 8 (Suppl. 2) J. OF THORACIC ONCOLOGY S1204 (2013)

- J.C. Hooton, *Carboxymethylcellulose Calcium in* HANDBOOK OF PHARMACEUTICAL EXCIPIENTS 117 (Raymond C. Rowe et al. eds., 6th ed. 2009)

- N. Nakagawa et al, *A phase 1/11 study with a highly selective ALK inhibitor CH5424802/RO5424802 in ALK-positive non-small cell lung cancer (NSCLC) patients: Updated safety and efficacy results from AF-001JP*, Poster Presented at the 49th Annual Meeting of the American Society of Clinical Oncology (ASCO), Chicago, IL, May 31, 2013 – June 4, 2013

- Patrice Wendling, *Alectinib active in ALK-positive, crizotinib-refractory NSCLC*, CHEST PHYSICIAN (October 9, 2013), https://www.mdedge.com/chestphysician/article/78177/lung-cancer/alectinib-active-alk-positive-crizotinib-refractory-nsclc

- P. Plumb, *Sodium Lauryl Sulfate in* HANDBOOK OF PHARMACEUTICAL EXCIPIENTS 651 (Raymond C. Rowe et al. eds., 6th ed. 2009)

- Sai-Hong I. Ou et al., *Consistent Therapeutic Efficacy of CH5424802/RO5424802 in Brain Metastases Among Crizotinib-Refractory ALK-Positive Non-small Cell Lung Cancer (NSCLC) Patients in an Ongoing Phase I/II Study (AF-002JG/NP28761, NCT01588028)*, 8 (Suppl. 2) J. OF THORACIC ONCOLOGY S200 (2013)

- Shirish Gadgeel et al., *Phase 1 Dose Escalation Study of a New ALK Inhibitor, CH542802/RO542802, in ALK+ Non-small Cell Lung Cancer (NSCLC) Patients Who Have Failed Crizotinib (AF-002JG/NP28761, NCT01588028)*, 8 (Suppl. 2) J. OF THORACIC ONCOLOGY S199 (2013)

- S. H. Ou, *Safety and efficacy analysis of RO542802/CH5424802 in anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) patients who have failed crizotinib in dose-finding phase I study (AF-002JG, NCT01588028)*, 29 (Suppl. 3) EUR. J. OF CANCER (2013)

- Takashi Seto et al., *CH5424802 (RO5424802) for patients with ALK-rearranged advanced non-small-cell lung cancer (AF-001JP study): a single arm, open-label, phase 1-2 study*, 14 LANCET ONCOLOGY 590 (2013)

- The ’514 patent and its associated publications (e.g., U.S. Patent Publication No. 2013/143877, PCT Publication No. WO2012/023597)

- The ’931 patent and its associated publications (e.g., U.S. Patent Publication No. 2012/143664, PCT Publication No. WO2010/143664)
- The ’922 patent

69. As a further example, every claim of the ’214 patent is invalid under the judicially-created doctrine of obviousness-type double patenting over the claims of the ’514, ’922, and/or ’931 patents in view of at least the prior art listed in Paragraph 68.

70. Fresenius is entitled to a declaratory judgment that each of the claims of the ’214 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112., et seq. and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability and the rules, regulations, and laws pertaining thereto.

71. Fresenius is entitled to an award of costs and expenses, including reasonable attorneys’ fees, to be assessed against Counterclaim Defendants in accordance with the provisions of 35 U.S.C. § 285 or such other authorities as the Court deems applicable.

PRAYER FOR RELIEF

WHEREFORE, Fresenius requests the Court to enter Judgment in its favor and against Plaintiffs as follows:

A. Dismissing all of Counterclaim Defendants’ claims with prejudice;

B. Adjudging that Fresenius has not and will not infringe any asserted claim of the patents-in-suit;

C. Adjudging that the asserted claims of the patents-in-suit are invalid;

D. Granting Fresenius judgment in its favor on Counterclaim Defendants’ claims;

E. Denying Counterclaim Defendants’ request for injunctive relief;

F. Declaring that Fresenius has not and will not infringe any asserted claim of the patents-in-suit;

G. Declaring that the asserted claims of the patents-in-suit are invalid;

H. Finding this to be an exceptional case under 35 U.S.C. § 285 and awarding Fresenius reasonable attorney fees and costs; and

I. Awarding Fresenius such other and further relief as this Court may deem just, proper or equitable.

Respectfully Submitted,

Dated: June 8, 2020

PHILLIPS, MCLAUGHLIN & HALL, P.A.

/s/ John C. Phillips, Jr.
John C. Phillips, Jr. (#110)
Megan C. Haney (#5016)
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pmhdelaw.com
mch@pmhdelaw.com

Of Counsel:
Daryl L. Wiesen
John T. Bennett
Eric T. Romeo
Christie L. Larochelle
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210
(617) 570-1000
dwiesen@goodwinlaw.com
jbennett@goodwinlaw.com
eromeo@goodwinlaw.com
clarochelle@goodwinlaw.com

Attorneys for Fresenius Kabi USA, LLC, Fresenius Kabi Oncology Limited, and Fresenius SE & Co. KGAA

CERTIFICATE OF SERVICE

I, John C. Philips, Jr., hereby certify that on June 8, 2020, this document was served on the persons listed below in the manner indicated.

BY EMAIL

Karen Jacobs (#2881)
Derek J. Fahnestock (#4705)
Cameron Clark (#6647)
MORRIS, NICHOLS, ARSHT & TUNNELL LLP

1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
kjacobs@mnat.com
dfahnestock@mnat.com
cclark@mnat.com

Nicholas Groombridge
Eric Alan Stone
Josephine Young
Crystal Lohmann Parker
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 373-2000

Saurabh Gupta
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
2001 K Street, NW
Washington, DC 20006
(202) 223-7300

/s/ John C. Philips Jr.
John C. Phillips, Jr. (#110)