IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION and ASTEX THERAPEUTICS LTD. Plaintiffs, v. MSN PHARMACEUTICALS INC. and MSN LABORATORIES PVT. LTD. Defendants.	)	C.A. No.: ____

COMPLAINT

Plaintiffs Novartis Pharmaceuticals Corporation ("Novartis") and Astex Therapeutics Ltd. ("Astex") (collectively, "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against defendants MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd. (collectively, "MSN" or "Defendants"). This action relates to Abbreviated New Drug Application ("ANDA") No. 215976 (the "MSN ANDA") filed by Defendants with the United States Food and Drug Administration ("FDA"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of 200 mg ribociclib tablets, generic versions of Plaintiffs' KISQALI® drug tablets (the "ANDA Product"), prior to the expiration of U.S. Patent Nos. 8,324,225 ("the '225 patent"), 8,415,355

("the '355 patent"), 8,685,980 ("the '980 patent"), 8,962,630 ("the '630 patent"), and 9,416,136 ("the '136 patent") (collectively, "the Asserted Patents").

PARTIES

A. Novartis Pharmaceuticals Corporation and Astex Therapeutics Ltd.

2. Plaintiff Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at One Health Plaza, East Hanover, New Jersey 07936-1080.

3. Plaintiff Astex Therapeutics Ltd. is a British corporation with its principal place of business at 436 Cambridge Science Park, Cambridge, CB4 0QA, United Kingdom.

4. Plaintiffs own all rights in the Asserted Patents.

5. Plaintiffs are engaged in the business of creating, developing, and bringing to market revolutionary drug therapies to benefit patients against serious diseases, including treatments for breast cancer. KISQALI® is such a treatment option. Novartis markets and sells KISQALI® in this judicial district and throughout the United States.

B. MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd.

6. Upon information and belief, MSN Pharmaceuticals Inc. is a corporation incorporated and existing under the laws of the State of Delaware, having a registered agent for the service of process at United States Corporation Agents, Inc., 221 N Broad St, Suite 3A, Middletown, Delaware 19709, and having a principal place of business at 20 Duke Rd, Piscataway, NJ 08854-3714. Upon information and belief, MSN Pharmaceuticals Inc. is a wholly owned subsidiary of MSN Laboratories Pvt. Ltd.

7. Upon information and belief, MSN Laboratories Pvt. Ltd. is a corporation

organized and existing under the laws of India, having a principal place of business at MSN House, Plot No.: C-24, Industrial Estate, Sanathnagar, Hyderabad, 500018, Telangana, India.

8. Upon information and belief, Defendants are a generic pharmaceutical organization that works in concert to develop, manufacture, market, and distribute generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

DEFENDANTS' INFRINGING ACTS

9. In a letter (the "MSN Notice Letter"), Defendants notified Plaintiffs (i) that MSN had submitted to the FDA ANDA No. 215976, seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of 200 mg ribociclib tablets in or into the United States, including Delaware, prior to the expiration of the '225 patent, the '355 patent, the '980 patent, the '630 patent, and the '136 patent, and (ii) that ANDA No. 215976 includes a certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) against the '225 patent, the '355 patent, the '980 patent, the '630 patent, and the '136 patent.

10. Defendants have committed an act of infringement in this judicial district by filing the MSN ANDA with the intent to make, use, sell, offer for sale, and/or import the ANDA Product in or into this judicial district prior to the expiration of the '225 patent, the '355 patent, the '980 patent, the '630 patent, and the '136 patent, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

11. Upon information and belief, MSN Laboratories Pvt. Ltd. acted in concert with and/or directed MSN Pharmaceuticals Inc. in the preparation and submission of the MSN ANDA and, if the MSN ANDA is approved, will act in concert with and direct MSN Pharmaceuticals Inc. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the

ANDA Product in or into the United States, including Delaware, prior to the expiration of the '225 patent, the '355 patent, the '980 patent, the '630 patent, and the '136 patent.

12. Upon information and belief, MSN Pharmaceuticals Inc. has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its parent, subsidiaries, agents, or affiliates, including MSN Laboratories Pvt. Ltd.; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

13. Upon information and belief, MSN Laboratories Pvt. Ltd. has systematic and continuous contacts with Delaware; has established distribution channels for drug products in Delaware; regularly and continuously conducts business in Delaware, including by selling drug products in Delaware, either directly or indirectly through its subsidiaries, agents, or affiliates, including MSN Pharmaceuticals Inc.; purposefully incorporated its wholly owned subsidiary MSN Pharmaceuticals Inc. in Delaware; has purposefully availed itself of the privilege of doing business in Delaware; and derives substantial revenue from the sale of drug products in Delaware.

14. MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd. have availed themselves of the legal protections of the State of Delaware by, among other things, conceding jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g.*, *Vanda Pharmaceuticals Inc. v. MSN Pharmaceuticals Inc.*, Civ.

Action No. 21-283 (D. Del. 2021); *Intercept Pharmaceuticals, Inc. et al v. MSN Laboratories Private Limited et al*, Civ. Action No. 20-1214 (D. Del. 2020).

JURISDICTION AND VENUE

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

16. This Court has personal jurisdiction over MSN Laboratories Pvt. Ltd. under Federal Rule of Civil Procedure 4(k)(2), because, upon information and belief, MSN Laboratories Pvt. Ltd. is organized under the laws of India and the exercise of personal jurisdiction over MSN Laboratories Pvt. Ltd. is consistent with the United States Constitution and laws.

17. This Court has personal jurisdiction over MSN Pharmaceuticals Inc. because MSN Pharmaceuticals Inc. is a corporation incorporated and existing under Delaware law.

18. This Court also has personal jurisdiction over MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd. because, upon information and belief, Defendants committed or aided, abetted, contributed to, or participated in the commission of tortious acts of patent infringement in preparing and submitting the MSN ANDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which acts will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

19. Upon information and belief, the effort to seek approval for the MSN ANDA and to manufacture, import, market, and/or sell Defendants' ANDA Product upon approval has been a cooperative and joint enterprise and venture between MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd.

20. This Court also has personal jurisdiction over MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd. because, upon information and belief, each such Defendant, independently or in concert, upon approval of the MSN ANDA, will market, distribute, offer for sale, and/or sell Defendants' ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of the ANDA Product in the State of Delaware.

21. This Court also has personal jurisdiction over MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd. because, upon information and belief, Defendants' ANDA Product, upon approval of the MSN ANDA, will be marketed, distributed, offered for sale, and/or sold in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which will have a substantial effect on Delaware.

22. This Court also has personal jurisdiction over MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd. because, upon information and belief, Defendants' affiliations with the State of Delaware, including MSN Pharmaceuticals Inc.'s incorporation in Delaware, MSN Pharmaceuticals Inc.'s availing itself, at MSN Laboratories Pvt. Ltd.'s direction, of the legal protections of the State of Delaware, and MSN Laboratories Pvt. Ltd.'s ownership of and actions in concert with MSN Pharmaceuticals Inc. are sufficiently continuous and systematic as to render Defendants at home in this forum.

23. Upon information and belief, MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd. operate as an integrated business with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products, including the ANDA Product, throughout the United States including in this judicial district.

24. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd.

25. Venue is proper in this Court because MSN Pharmaceuticals Inc. is incorporated under the laws of the State of Delaware and therefore resides in this judicial district, and MSN Laboratories Pvt. Ltd. is a foreign entity who may be sued in any judicial district, including Delaware. 28 U.S.C. § 1400(b); 28 U.S.C. § 1391(c)(3). Defendants have also previously conceded that venue is proper in Delaware for at least the cases listed above and have conceded that venue is proper in Delaware for purposes of the counterclaims filed in those cases.

THE PATENTS-IN-SUIT AND KISQALI®

26. Plaintiffs are the owners of the ’225 patent, titled “Pyrrolopyrimidine Compounds and Their Uses.” The ’225 patent was duly and legally issued on December 4, 2012. A true and correct copy of the ’225 patent is attached hereto as **Exhibit A**.

27. The ’225 patent generally claims a compound of Formula I or a pharmaceutically acceptable salt thereof and a pharmaceutical composition comprising the same.

28. Plaintiffs are the owners the ’355 patent, titled “Pyrrolopyrimidine Compounds and Their Uses.” The ’355 patent was duly and legally issued on April 9, 2013. A true and correct copy of the ’355 patent is attached hereto as **Exhibit B**.

29. The ’355 patent generally claims a compound 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide (“ribociclib”) or a pharmaceutically acceptable salt thereof and a pharmaceutical composition comprising the same.

30. Plaintiffs are the owners of the ’980 patent, titled “Pyrrolopyrimidine Compounds and Their Uses.” The ’980 patent was duly and legally issued on April 1, 2014. A true and correct copy of the ’980 patent is attached hereto as **Exhibit C**.

31. The ’980 patent generally claims a compound of formula I or a pharmaceutically acceptable salt thereof, a compound of formula I(a) or a pharmaceutically acceptable salt thereof, and a pharmaceutical composition comprising the same.

32. Plaintiffs are the owners of the ’630 patent, titled “Pyrrolopyrimidine Compounds and Their Uses.” The ’630 patent was duly and legally issued on February 24, 2015. A true and correct copy of the ’630 patent is attached hereto as **Exhibit D**.

33. The ’630 patent generally claims a method for the treatment of cancer by inhibiting of a cyclin-dependent kinase, comprising administering an effective amount of 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide or a pharmaceutically acceptable salt thereof.

34. Plaintiffs are the owners of the ’136 patent, titled “Pyrrolopyrimidine Compounds and Their Uses.” The ’136 patent was duly and legally issued on August 16, 2016. A true and correct copy of the ’136 patent is attached hereto as **Exhibit E**.

35. The ’136 patent generally claims methods for the treatment of cancer by inhibiting cyclin-dependent kinase 4 comprising administering a compound of formula I or a pharmaceutically acceptable salt thereof and a compound of formula I(a) or a pharmaceutically acceptable salt thereof.

36. Novartis is the holder of New Drug Application (“NDA”) No. 209092 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of

KISQALI® (ribociclib) tablets. KISQALI® is currently indicated for use in combination with (i) an aromatase inhibitor for treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER-2)-negative advanced or metastatic breast cancer, as an initial endocrine based therapy; (ii) an aromatase inhibitor for the treatment of pre/perimenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy; and (iii) fulvestrant for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine based therapy or following disease progression on endocrine therapy.

37. One or more claims of each of the Asserted Patents cover KISQALI® and/or its use.

38. The FDA's official publication of approved drugs (the "Orange Book") lists the Asserted Patents in connection with KISQALI®.

INFRINGEMENT OF THE ASSERTED PATENTS

FIRST COUNT FOR PATENT INFRINGEMENT ('225 PATENT UNDER § 271(e)(2)(A))

39. Plaintiffs reallege, and incorporate in full herein, each preceding paragraph.

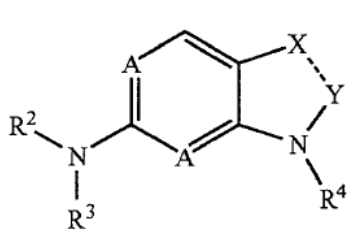
40. The '225 patent, entitled "Pyrrolopyrimidine Compounds and Their Uses," was issued on December 4, 2012. The '225 patent identifies Christopher Thomas Brain, Moo Je Sung, and Gebhard Thoma as inventors of the claimed subject matter. A true and correct copy of the '225 patent is attached hereto as **Exhibit A**.

41. Plaintiffs are the owners of the '225 patent by virtue of assignment.

42. The '225 patent expires on June 17, 2028, which includes 390 days of Patent Term Adjustment under 35 U.S.C. § 154(b), excluding any pediatric exclusivity.

43. The ’225 patent generally claims a compound of Formula I or a pharmaceutically acceptable salt thereof and a pharmaceutical composition comprising the same.

44. Claim 1 recites: A compound of Formula I:



(I)

or a pharmaceutically acceptable salt thereof, wherein:

the dashed line indicates a double bond;

A is N;

R^2 is hydrogen and R^3 is selected from the group consisting of hydrogen, hydroxyl, C_1-C_3-alkyl, C_3-C_8-cycloalkyl, heterocyclyl, aryl, heteroaryl, substituted C_1-C_3-alkyl, substituted C_3-C_8-cycloalkyl, substituted heterocyclyl, substituted aryl and substituted heteroaryl;

R^4 is selected from the group consisting of hydrogen, branched C_1-C_5-alkyl, branched C_1-C_5-alkyl substituted by phenyl and C_3-C_6-cycloalkyl;

X is CR^{11} and Y is CR^{12};

R^{11} is hydrogen or C_1-C_3-alkyl and R^{12} is $BC(O)NR^{13}R^{14}$;

wherein B is a bond, C_1-C_3-alkyl or branched C_1-C_3-alkyl;

wherein R^{13} and R^{14} are each, independently, selected from the group consisting of hydrogen, C_1-C_3-alkyl, C_3-C_8-cycloalkyl, heterocyclyl, aryl, heteroaryl, substituted alkyl, substituted cycloalkyl, substituted heterocyclyl, substituted aryl, and substituted heteroaryl.

45. The FDA approved NDA No. 209092 on March 13, 2017, for KISQALI® (ribociclib tablets) for use in combination with an aromatase inhibitor for the treatment of pre/perimenopausal or postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, as initial endocrine-based therapy; or fulvestrant for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy.

46. Ribociclib tablets are marketed in the United States under the trademark KISQALI®.

47. FDA-approved KISQALI® comprises ribociclib succinate, which is a pharmaceutically acceptable salt of ribociclib, a compound of Formula I according to claim 1 of the ’225 patent.

48. The ’225 patent is listed in the Orange Book for NDA No. 209092 for KISQALI®. At least one claim, including claim 1, of the ’225 patent reads on FDA-approved KISQALI® (ribociclib tablets).

49. Upon information and belief, Defendants submitted ANDA No. 215976 to the FDA, under Section 505(j) of the Federal Food, Drug and Cosmetic Act (“the Act”), and 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic ribociclib tablets containing 200 mg of ribociclib (upon information and belief in the form of ribociclib succinate) in or into the United States, including Delaware.

50. Upon information and belief, Defendants' proposed generic ribociclib tablets that are the subject of ANDA No. 215976 contain ribociclib succinate, which is a pharmaceutically acceptable salt of ribociclib, which in turn is a compound of Formula I according to claim 1 of the '225 patent. Defendants' generic ribociclib succinate tablets will therefore directly infringe at least claim 1 of the '225 patent.

51. Plaintiffs received the MSN Notice Letter, purporting to include a Notice of Certification for ANDA No. 215976 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '225 patent. The MSN Notice Letter did not allege non-infringement as to at least claim 1 of the '225 patent.

52. Upon information and belief, Defendants seek FDA approval for generic versions of the ribociclib tablets that are claimed in the '225 patent.

53. Upon information and belief, Defendants' generic ribociclib tablets, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim, including claim 1, of the '225 patent under 35 U.S.C. § 271(a).

54. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim, including claim 1, of the '225 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 215976 seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic product before the expiration date of the '225 patent. Upon information and belief, the products described in ANDA No. 215976 would infringe, either literally or under the doctrine of equivalents, at least one claim, including claim 1, of the '225 patent under 35 U.S.C. § 271(e)(2)(A).

55. Upon information and belief, Defendants' actions relating to Defendants' ANDA

No. 215976 complained of herein were done by and for the benefit of Defendants.

56. Upon information and belief, Defendants had actual knowledge of the ’225 patent prior to the submission of ANDA No. 215976 to the FDA.

57. If Defendants’ marketing and sale of generic ribociclib tablets prior to expiration of the ’225 patent and all other relevant activities are not enjoined, the Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

SECOND COUNT (DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’225 PATENT)

58. Plaintiffs reallege, and incorporate in full herein, each preceding paragraph.

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

60. A definite and concrete, actual, substantial, and continuing justiciable controversy involving adverse legal interests between Plaintiffs and Defendants having such immediacy and reality exists such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

61. This controversy is amenable to specific relief through a decree of a conclusive character.

62. Upon information and belief, Defendants had actual knowledge of the ’225 patent prior to the submission of ANDA No. 215976 to the FDA.

63. Upon information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Defendants’ ANDA Product prior to the expiration of the ’225 patent, including Defendants’

filing of ANDA No. 215976, with the intent of competing against Plaintiffs' Kisqali products in the United States.

64. Defendants' actions, including, but not limited to, the development of Defendants' ANDA Product, the content of and instructions in Defendants' proposed label, the filing of ANDA No. 215976, and engaging in litigation to manufacture, offer to sell, sell and/or import Defendants' ANDA Product prior to patent expiry, indicate a refusal to change the course of its action and reliably predict that Defendants will continue to make substantial preparations to manufacture, sell, offer to sell, and/or import Defendants' ANDA Product.

65. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Defendants' ANDA Product prior to the expiration of the '225 patent will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '225 patent.

66. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Defendants' ANDA Product prior to the expiration of the '225 patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement under 35 U.S.C. § 271(a), (b), and/or (c) respectively of the '225 patent.

THIRD COUNT FOR PATENT INFRINGEMENT ('355 PATENT UNDER § 271(e)(2)(A))

67. Plaintiffs reallege, and incorporate in full herein, each preceding paragraph.

68. The '355 patent, entitled "Pyrrolopyrimidine Compounds and Their Uses," was issued on April 9, 2013. The '355 patent identifies Christopher Thomas Brain, Moo Je Sung, and Bharat Lagu as inventors of the claimed subject matter. A true and correct copy of the '355

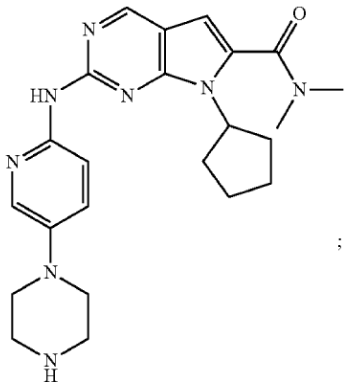
patent is attached hereto as **Exhibit B**.

69. Plaintiffs are the owners of the ’355 patent by virtue of assignment.

70. The ’355 patent expires on February 19, 2031, which includes Patent Term Adjustment under 35 U.S.C. § 154, but excludes any Patent Term Extension under 35 U.S.C. § 156[1] and pediatric exclusivity.

71. The ’355 patent generally claims 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide (“ribociclib”) or a pharmaceutically acceptable salt thereof and a pharmaceutical composition comprising the same.

72. Claim 1 recites: A compound 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide of the formula



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or a pharmaceutically acceptable salt thereof.

73. FDA-approved KISQALI® comprises ribociclib succinate, which is a pharmaceutically acceptable salt of ribociclib, the compound named in claim 1 of the ’355 patent.

[1] Patentees expect a certificate under 35 U.S.C. § 156 to be issued shortly, which will extend the term of the ’355 patent to March 13, 2031.

74. The ’355 patent is listed in the Orange Book for NDA No. 209092 for KISQALI®. At least one claim, including claim 1, of the ’355 patent reads on FDA-approved KISQALI® (ribociclib tablets).

75. Upon information and belief, Defendants submitted ANDA No. 215976 to the FDA, under Section 505(j) of the Act, and 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of generic ribociclib tablets containing 200 mg of ribociclib (upon information and belief in the form of ribociclib succinate) in or into the United States, including Delaware.

76. Upon information and belief, Defendants’ proposed generic ribociclib tablets that are the subject of ANDA No. 215976 contain ribociclib succinate, which is a pharmaceutically acceptable salt of ribociclib, which in turn is 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide recited in claim 1 of the ’355 patent. Defendants’ generic ribociclib succinate tablets will therefore directly infringe at least claim 1 of the ’355 patent.

77. Plaintiffs received the MSN Notice Letter, purporting to include a Notice of Certification for ANDA No. 215976 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the ’355 patent. The MSN Notice Letter did not allege non-infringement as to at least claim 1 of the ’355 patent.

78. Upon information and belief, Defendants seek FDA approval for generic versions of the ribociclib tablets that are claimed in the ’355 patent.

79. Upon information and belief, Defendants’ generic ribociclib tablets, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one

claim, including claim 1, of the ’355 patent under 35 U.S.C. § 271(a).

80. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim, including claim 1, of the ’355 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 215976 seeking approval to manufacture, use, import, offer to sell or sell Defendants’ generic ribociclib tablets before the expiration date of the ’355 patent. Upon information and belief, the generic products described in ANDA No. 215976 would infringe, either literally or under the doctrine of equivalents, at least one claim, including claim 1, of the ’355 patent under 35 U.S.C. § 271(e)(2)(A).

81. Upon information and belief, Defendants’ actions relating to Defendants’ ANDA No. 215976 complained of herein were done by and for the benefit of Defendants.

82. Upon information and belief, Defendants had actual knowledge of the ’355 patent prior to the submission of ANDA No. 215976 to the FDA.

83. If Defendants’ marketing and sale of generic ribociclib tablets prior to expiration of the ’355 patent and all other relevant activities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

FOURTH COUNT (DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’355 PATENT)

84. Plaintiffs reallege, and incorporate in full herein, each preceding paragraph.

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

86. A definite and concrete, actual, substantial, and continuing justiciable controversy involving adverse legal interests between Plaintiffs and Defendants having such immediacy and reality exists such that the Court may entertain Plaintiffs’ request for declaratory relief consistent

with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

87. This controversy is amenable to specific relief through a decree of a conclusive character.

88. Upon information and belief, Defendants had actual knowledge of the ’355 patent prior to the submission of ANDA No. 215976 to the FDA.

89. Upon information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Defendants’ ANDA Product prior to the expiration of the ’355 patent, including Defendants’ filing of ANDA No. 215976, with the intent of competing against Plaintiffs’ Kisqali products in the United States.

90. Defendants’ actions, including, but not limited to, the development of Defendants’ ANDA Product, the content of and instructions in Defendants’ proposed label, the filing of ANDA No. 215976, and engaging in litigation to manufacture, offer to sell, sell and/or import Defendants’ ANDA Product prior to patent expiry, indicate a refusal to change the course of its action and reliably predict that Defendants will continue to make substantial preparations to manufacture, sell, offer to sell, and/or import Defendants’ ANDA Product.

91. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Defendants’ ANDA Product prior to the expiration of the ’355 patent will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’355 patent.

92. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Defendants’ ANDA Product prior

to the expiration of the ’355 patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement under 35 U.S.C. § 271(a), (b), and/or (c) respectively of the ’355 patent.

FIFTH COUNT FOR PATENT INFRINGEMENT (’980 PATENT UNDER §271(e)(2)(A))

93. Plaintiffs reallege, and incorporate in full herein, each preceding paragraph.

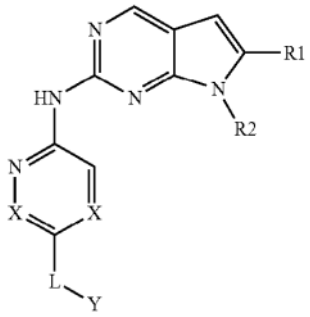
94. The ’980 patent, entitled “Pyrrolopyrimidine Compounds and Their Uses,” was issued on April 1, 2014. The ’980 patent identifies Gilbert Ebai Besong, Christopher Thomas Brain, Clinton Alan Brooks, Miles Stuart Congreve, Claudio Dagostin, Guo He, Ying Hou, Steven Howard, Yue Li, Yipin Lu, Paul Neil Mortenson, Troy D. Smith, Moo Je Sung, Steven John Woodhead, Wojciech Wrona, and Bharat Lagu as inventors of the claimed subject matter. A true and correct copy of the ’980 patent is attached hereto as **Exhibit C**.

95. Plaintiffs are the owners of the ’980 patent by virtue of assignment.

96. The ’980 patent expires on May 25, 2030, which includes 278 days of Patent Term Adjustment under 35 U.S.C. § 154(b), but excludes any pediatric exclusivity.

97. The ’980 patent generally claims a compound of formula I or a pharmaceutically acceptable salt thereof, and a pharmaceutical composition comprising the same, as well as a compound of formula I(a) or a pharmaceutically acceptable salt thereof, and a pharmaceutical composition comprising the same.

98. Claim 1 recites: A compound of formula I:



I

or a pharmaceutically acceptable salt thereof, wherein

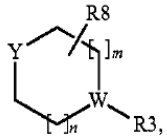
X is CR^9;

R^1 is $CONR^5R^6$, and R^5 and R^6 are C_{1-8}alkyl;

R^2 is C_{3-14}cycloalkyl;

L is a bond, C_{1-8}alkylene, C(O), or C(O)NH, and wherein L may be substituted or unsubstituted;

Y is H, R^{11}, $NR^{12}R^{13}$, OH, or Y is part of the following group



where Y is CR^9 or N;

where 0-3 R^8 may be present, and R^8 is C_{1-8}alkyl, oxo, halogen, or two or more R^8 may form a bridged alkyl group;

W is CR^9, or N;

R^3 is H, C_{1-8}alkyl, C_{1-8}alkylR^{14}, C_{3-14}cycloalkyl, $C(O)C_{1-8}$ alkyl, C_{1-8}haloalkyl, C_{1-8}alkylOH, $C(O)NR^{14}R^{15}$, C_{1-8}cyanoalkyl, $C(O)R^{14}$, C_{0-8}alkyl$C(O)C_{0-8}$alkyl$NR^{14}R^{15}$, C_{0-8}alkyl$C(O)OR^{14}$,

$NR^{14}R^{15}$, $SO_2C_{1\text{-}8}$alkyl, $C_{1\text{-}8}$alkyl$C_{3\text{-}14}$cycloalkyl, $C(O)C_{1\text{-}8}$alkyl$C_{3\text{-}14}$cycloalkyl, $C_{1\text{-}8}$alkoxy, or OH which may be substituted or unsubstituted when R^3 is not H;

R^9 is H or halogen;

R^{11}, R^{12}, R^{13}, R^{14}, and R^{15} are each independently selected from H, $C_{1\text{-}8}$alkyl, $C_{3\text{-}14}$ cycloalkyl, a 3-14 membered cycloheteroalkyl group, a $C_{6\text{-}14}$ aryl group, a 5-14 membered heteroaryl group, alkoxy, C(O)H, C(NH)OH, $C(NH)OCH_3$, $C(O)C_{1\text{-}3}$alkyl, $C_{1\text{-}8}$alkylNH_2, and $C_{1\text{-}6}$alkylOH, and wherein R^{11}, R^{12}, and R^{13}, R^{14}, and R^{15} when not H may be substituted or unsubstituted;

m and n are independently 0-2; and

wherein L, R^3, R^{11}, R^{12}, and R^{13}, R^{14}, and R^{15} may be substituted with one or more of $C_{1\text{-}8}$alkyl, $C_{2\text{-}8}$alkenyl, $C_{2\text{-}8}$alkynyl, $C_{3\text{-}14}$cycloalkyl, 5-14 membered heteroaryl group, $C_{6\text{-}14}$aryl group, a 3-14 membered cycloheteroalkyl group, OH, (O), CN, alkoxy, halogen, or NH_2.

99. FDA-approved KISQALI® comprises ribociclib succinate, which is a pharmaceutically acceptable salt of ribociclib, a compound of formula I according to claim 1 of the ’980 patent.

100. The ’980 patent is listed in the Orange Book for NDA No. 209092 for KISQALI®. At least one claim, including claim 1, of the ’980 patent reads on FDA-approved KISQALI® (ribociclib tablets).

101. Upon information and belief, Defendants submitted ANDA No. 215976 to the FDA, under Section 505(j) of the Act, and 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of generic ribociclib tablets containing 200 mg of ribociclib (upon information and belief in the form of ribociclib succinate) in or into the United States, including Delaware.

102. Upon information and belief, Defendants' proposed generic ribociclib tablets that are the subject of ANDA No. 215976 contain ribociclib succinate, which is a pharmaceutically acceptable salt of ribociclib, which in turn is a compound of formula I according to claim 1 of the '980 patent. Defendants' generic ribociclib succinate tablets will therefore directly infringe at least claim 1 of the '980 patent.

103. Plaintiffs received the MSN Notice Letter, purporting to include a Notice of Certification for ANDA No. 215976 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '980 patent. The MSN Notice Letter did not allege non-infringement as to at least claim 1 of the '980 patent.

104. Upon information and belief, Defendants seek FDA approval for generic versions of the ribociclib tablets that are claimed in the '980 patent.

105. Upon information and belief, Defendants' generic ribociclib tablets, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim, including claim 1, of the '980 patent under 35 U.S.C. § 271(a).

106. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim, including claim 1, of the '980 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 215976 seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic ribociclib tablets before the expiration date of the '980 patent. Upon information and belief, the generic products described in ANDA No. 215976 would infringe, either literally or under the doctrine of equivalents, at least one claim including claim 1 of the '980 patent under 35 U.S.C. § 271(e)(2)(A).

107. Upon information and belief, Defendants' actions relating to Defendants' ANDA

No. 215976 complained of herein were done by and for the benefit of Defendants.

108. Upon information and belief, Defendants had actual knowledge of the ’980 patent prior to the submission of ANDA No. 215976 to the FDA.

109. If Defendants’ marketing and sale of generic ribociclib tablets prior to expiration of the ’980 patent and all other relevant activities are not enjoined, the Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

SIXTH COUNT (DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’980 PATENT)

110. Plaintiffs reallege, and incorporate in full herein, each preceding paragraph.

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

112. A definite and concrete, actual, substantial, and continuing justiciable controversy involving adverse legal interests between Plaintiffs and Defendants having such immediacy and reality exists such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

113. This controversy is amenable to specific relief through a decree of a conclusive character.

114. Upon information and belief, Defendants had actual knowledge of the ’980 patent prior to the submission of ANDA No. 215976 to the FDA.

115. Upon information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Defendants’ ANDA Product prior to the expiration of the ’980 patent, including Defendants’ filing

of ANDA No. 215976, with the intent of competing against Plaintiffs' Kisqali products in the United States.

116. Defendants' actions, including, but not limited to, the development of Defendants' ANDA Product, the content of and instructions in Defendants' proposed label, the filing of ANDA No. 215976, and engaging in litigation to manufacture, offer to sell, sell and/or import Defendants' ANDA Product prior to patent expiry, indicate a refusal to change the course of its action and reliably predict that Defendants will continue to make substantial preparations to manufacture, sell, offer to sell, and/or import Defendants' ANDA Product.

117. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Defendants' ANDA Product prior to the expiration of the '980 patent will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '980 patent.

118. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Defendants' ANDA Product prior to the expiration of the '980 patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement under 35 U.S.C. § 271(a), (b), and/or (c) respectively of the '980 patent.

SEVENTH COUNT FOR PATENT INFRINGEMENT ('630 PATENT UNDER § 271(e)(2)(A))

119. Plaintiffs reallege, and incorporate in full herein, each preceding paragraph.

120. The '630 patent, entitled "Pyrrolopyrimidine Compounds and Their Uses," was issued on February 24, 2015. The '630 patent identifies Christopher Thomas Brain, Moo Je Sung, and Bharat Lagu as inventors of the claimed subject matter. A true and correct copy of the '630 patent is attached hereto as **Exhibit D**.

121. Plaintiffs are the owners of the ’630 patent by virtue of assignment.

122. The ’630 patent expires on December 9, 2029, which includes 110 days of Patent Term Adjustment under 35 U.S.C. § 154(b), but excludes any pediatric exclusivity.

123. The ’630 patent generally claims a method for the treatment of cancer by inhibiting of a cyclin-dependent kinase (CDK), comprising administering an effective amount of 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide or a pharmaceutically acceptable salt thereof.

124. Claim 1 recites: A method for the treatment of cancer by inhibiting of a cyclin-dependent kinase (CDK) comprising administration of an effective amount of 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide or a pharmaceutically acceptable salt thereof to a subject in need of treatment thereof.

125. The ’630 patent is listed in the Orange Book for NDA No. 209092 for KISQALI®. At least one claim, including claim 1, of the ’630 patent reads on FDA-approved KISQALI® (ribociclib tablets).

126. Plaintiffs received the MSN Notice Letter, purporting to include a Notice of Certification for ANDA No. 215976 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the ’630 patent. The MSN Notice Letter did not allege that it would not indirectly infringe at least claim 1 of the ’630 patent.

127. Upon information and belief, Defendants seek FDA approval for methods of use of generic versions of the ribociclib tablets that are claimed in the ’630 patent.

128. Upon information and belief, Defendants’ generic ribociclib tablets, if approved

and marketed in the United States, will infringe, either literally or under the doctrine of equivalents, at least one claim, including claim 1, of the ’630 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

129. Ribociclib is 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide as recited in claim 1 of the ’630 patent. FDA-approved KISQALI® comprises ribociclib succinate, which is a pharmaceutically acceptable salt of ribociclib as recited in claim 1 of the ’630 patent. Ribociclib succinate is a CDK inhibitor approved for treatment of pre/perimenopausal or postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. Claim 1 is drawn to a method for the treatment of cancer by inhibiting of a cyclin-dependent kinase (CDK) comprising administration of an effective amount of ribociclib or a pharmaceutically acceptable salt thereof to a subject in need of treatment thereof.

130. Upon information and belief, Defendants filed ANDA No. 215976 seeking authorization to commercially manufacture, use, import, offer to sell or sell Defendants’ generic ribociclib tablets in the United States. Upon information and belief, if the FDA approves ANDA No. 215976, physicians, health care providers, and/or patients will use Defendants’ generic ribociclib tablets according to Defendants’ provided instructions and/or label and will directly infringe, either literally or under the doctrine of equivalents, at least one claim, including claim 1 of the ’630 patent.

131. Upon information and belief, if the FDA approves ANDA No. 215976, Defendants know and intend that physicians, health care providers, and/or patients will prescribe,

administer, and/or use Defendants' generic ribociclib tablets according to Defendants' provided instructions and/or label in an infringing manner, and will therefore induce infringement of at least one claim, including claim 1, of the '630 patent with the requisite intent under 35 U.S.C. §271 (b).

132. Upon information and belief, if the FDA approves ANDA No. 215976, Defendants will sell or offer to sell generic ribociclib tablets with provided instructions and/or label in an infringing manner, wherein Defendants' generic ribociclib tablets are a material part of the claimed invention, wherein Defendants know that physicians will prescribe, health care providers will administer, and/or patients will use Defendants' generic ribociclib tablets in accordance with Defendants' provided instructions and/or label, wherein such use will directly infringe at least one claim, including claim 1, of the '630 patent, and wherein generic ribociclib tablets are not staple articles or commodities of commerce suitable for substantial non-infringing use. Upon information and belief, Defendants will thus contribute to the infringement of at least one claim, including claim 1, of the '630 patent under 35 U.S.C. § 271(c).

133. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 215976 complained of herein were done by and for the benefit of Defendants.

134. Upon information and belief, Defendants had actual knowledge of the '630 patent prior to the submission of ANDA No. 215976 to the FDA.

135. If Defendants' marketing and sale of generic ribociclib tablets prior to expiration of the '630 patent and all other relevant activities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

EIGHTH COUNT (DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '630 PATENT)

136. Plaintiffs reallege, and incorporate in full herein, each preceding paragraph.

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

138. A definite and concrete, actual, substantial, and continuing justiciable controversy involving adverse legal interests between Plaintiffs and Defendants having such immediacy and reality exists such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

139. This controversy is amenable to specific relief through a decree of a conclusive character.

140. Upon information and belief, Defendants had actual knowledge of the '630 patent prior to the submission of ANDA No. 215976 to the FDA.

141. Upon information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Defendants' ANDA Product prior to the expiration of the '630 patent, including Defendants' filing of ANDA No. 215976, with the intent of competing against Plaintiffs' Kisqali products in the United States.

142. Defendants' actions, including, but not limited to, the development of Defendants' ANDA Product, the content of and instructions in Defendants' proposed label, the filing of ANDA No. 215976, and engaging in litigation to manufacture, offer to sell, sell and/or import Defendants' ANDA Product prior to patent expiry, indicate a refusal to change the course of its action and

reliably predict that Defendants will continue to make substantial preparations to manufacture, sell, offer to sell, and/or import Defendants' ANDA Product.

143. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Defendants' ANDA Product prior to the expiration of the '630 patent will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '630 patent.

144. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Defendants' ANDA Product prior to the expiration of the '630 patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement under 35 U.S.C. § 271(a), (b), and/or (c) respectively of the '630 patent.

NINTH COUNT FOR PATENT INFRINGEMENT ('136 PATENT UNDER § 271(e)(2)(A))

145. Plaintiffs reallege, and incorporate in full herein, each preceding paragraph.

146. The '136 patent, entitled "Pyrrolopyrimidine Compounds and Their Uses," was issued on August 16, 2016. The '136 patent identifies Gilbert Besong, Christopher Thomas Brain, Clinton A Brooks, Miles Stuart Congreve, Claudio Dagostin, Guo He, Ying Hou, Steven Howard, Yue Li, Yipin Lu, Paul Mortenson, Troy Smith, Moo Je Sung, Steven Woodhead, Wojciech Wrona, and Bharat Lagu as inventors of the claimed subject matter. A true and correct copy of the '136 patent is attached hereto as **Exhibit E**.

147. Plaintiffs are the owners of the '136 patent by virtue of assignment.

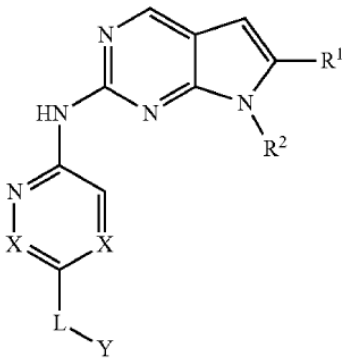
148. The '136 patent expires on August 20, 2029, excluding any pediatric exclusivity.

149. The '136 patent generally claims methods for the treatment of cancer by inhibiting cyclin-dependent kinase 4 comprising administering a compound of formula I or a

pharmaceutically acceptable salt thereof and methods for the treatment of cancer by inhibiting cyclin-dependent kinase 4 comprising administering a compound of formula I(a) or a pharmaceutically acceptable salt thereof.

150. Claim 1 recites: A method for the treatment of cancer by inhibiting cyclin-dependent kinase 4 comprising administering a compound of formula I, or a pharmaceutically acceptable salt thereof, to a subject in need thereof:

I



,

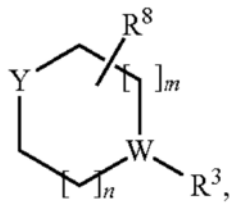
wherein X is CR^9;

R^1 is $CONR^5R^6$, and R^5 and R^6 are $C_{1\text{-}8}$alkyl;

R^2 is $C_{3\text{-}14}$cycloalkyl;

L is a bond, $C_{1\text{-}8}$alkylene, C(O), or C(O)NH, and wherein L may be substituted or unsubstituted;

Y is H, OH, or Y is part of the following group



where Y is N and W is CR^9, or N;

where 0-2 R^8 may be present, and R^8 is C_{1-8}alkyl, oxo, or two or more R^8 may form a bridged alkyl group;

R^3 is H, C_{1-8}alkyl, C_{3-14}cycloalkyl, $C(O)C_{1-8}$ alkyl, C_{1-8}alkylOH, C_{1-8}cyanoalkyl, C_{0-8}alkyl$C(O)C_{0-8}$alkyl$NR^{14}R^{15}$, C_{0-8}alkyl$C(O)OR^{14}$, $NR^{14}R^{15}$, C_{1-8}alkylC_{3-14}cycloalkyl, $C(O)C_{1-8}$alkylC_{3-14}cycloalkyl, C_{1-8}alkylR^{14}, C_{1-8}haloalkyl, or $C(O)R^{14}$, which may be substituted with one or more of OH, CN, F, or NH_2 , and wherein R^{14} and R^{15} are each independently selected from H, C_{1-8}alkyl, C_{3-14}cycloalkyl, alkoxy, $C(O)C_{1-3}$alkyl, C_{1-8}alkylNH_2, or C_{1-6} alkylOH;

R^9 is H or halogen;

m and n are independently 0-2; and

wherein L may be substituted with one or more of C_{1-8}alkyl, C_{2-8}alkenyl, C_{2-8}alkynyl, C_{3-14}cycloalkyl, 5-14 membered heteroaryl group, C_{6-14}aryl group, a 3-14 membered cycloheteroalkyl group, OH, (O), CN, alkoxy, halogen, or NH_2.

151. The ’136 patent is listed in the Orange Book for NDA No. 209092 for KISQALI®. At least one claim, including claim 1, of the ’136 patent reads on FDA-approved KISQALI® (ribociclib tablets).

152. Plaintiffs received the MSN Notice Letter, purporting to include a Notice of Certification for ANDA No. 215976 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the ’136 patent. The MSN Notice Letter did not allege that it did not indirectly infringe at least claim 1 of the ’136 patent.

153. Upon information and belief, Defendants seek FDA approval for methods of use of generic versions of the ribociclib tablets that are claimed in the ’136 patent.

154. Upon information and belief, Defendants' generic ribociclib tablets, if approved and marketed in the United States, will infringe, either literally or under the doctrine of equivalents, at least one claim, including claim 1, of the '136 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

155. Ribociclib is a compound of formula I as recited in claim 1 of the '136 patent. FDA-approved KISQALI® comprises ribociclib succinate, which is a pharmaceutically acceptable salt of ribociclib as recited in claim 1 of the '136 patent. Ribociclib succinate is a CDK4 inhibitor approved for treatment of pre/perimenopausal or postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. Claim 1 is drawn to a method for the treatment of cancer by inhibiting cyclin-dependent kinase 4 comprising administering a compound of formula I, or a pharmaceutically acceptable salt thereof, to a subject in need thereof.

156. Upon information and belief, Defendants filed ANDA No. 215976 seeking authorization to commercially manufacture, use, import, offer to sell or sell Defendants' generic ribociclib tablets in the United States. Upon information and belief, if the FDA approves ANDA No. 215976, physicians, health care providers, and/or patients will use Defendants' generic ribociclib tablets according to Defendants' provided instructions and/or label and will directly infringe, either literally or under the doctrine of equivalents, at least one claim, including claim 1, of the '136 patent.

157. Upon information and belief, if the FDA approves ANDA No. 215976, Defendants know and intend that physicians, health care providers, and/or patients will prescribe, administer, and/or use Defendants' generic ribociclib tablets according to Defendants' provided

instructions and/or label in an infringing manner, and will therefore induce infringement of at least one claim, including claim 1, of the ’136 patent with the requisite intent under 35 U.S.C. §271 (b).

158. Upon information and belief, if the FDA approves ANDA No. 215976, Defendants will sell or offer to sell generic ribociclib tablets with provided instructions and/or label in an infringing manner, wherein Defendants’ generic ribociclib tablets are a material part of the claimed invention, wherein Defendants know that physicians will prescribe, health care providers will administer, and/or patients will use Defendants’ generic ribociclib tablets in accordance with Defendants’ provided instructions and/or label, wherein such use will directly infringe at least one claim, including claim 1, of the ’136 patent, and wherein Defendants’ generic ribociclib tablets are not staple articles or commodities of commerce suitable for substantial non-infringing use. Upon information and belief, Defendants will thus contribute to the infringement of at least one claim, including claim 1, of the ’136 patent under 35 U.S.C. § 271(c).

159. Upon information and belief, Defendants’ actions relating to Defendants’ ANDA No. 215976 complained of herein were done by and for the benefit of Defendants.

160. Upon information and belief, Defendants had actual knowledge of the ’136 patent prior to the submission of ANDA No. 215976 to the FDA.

161. If Defendants’ marketing and sale of generic ribociclib tablets prior to expiration of the ’136 patent and all other relevant activities are not enjoined, the Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

TENTH COUNT (DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '136 PATENT)

162. Plaintiffs reallege, and incorporate in full herein, each preceding paragraph.

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

164. A definite and concrete, actual, substantial, and continuing justiciable controversy involving adverse legal interests between Plaintiffs and Defendants having such immediacy and reality exists such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

165. This controversy is amenable to specific relief through a decree of a conclusive character.

166. Upon information and belief, Defendants had actual knowledge of the '136 patent prior to the submission of ANDA No. 215976 to the FDA.

167. Upon information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Defendants' ANDA Product prior to the expiration of the '136 patent, including Defendants' filing of ANDA No. 215976, with the intent of competing against Plaintiffs' Kisqali products in the United States.

168. Defendants' actions, including, but not limited to, the development of Defendants' ANDA Product, the content of and instructions in Defendants' proposed label, the filing of ANDA No. 215976, and engaging in litigation to manufacture, offer to sell, sell and/or import Defendants' ANDA Product prior to patent expiry, indicate a refusal to change the course of its action and

reliably predict that Defendants will continue to make substantial preparations to manufacture, sell, offer to sell, and/or import Defendants' ANDA Product.

169. Any commercial manufacture, use, offer for sale, sale, and/or importation of the Defendants' ANDA Product prior to the expiration of the '136 patent will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '136 patent.

170. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Defendants' ANDA Product prior to the expiration of the '136 patent will constitute direct infringement, contributory infringement, and/or active inducement of infringement under 35 U.S.C. § 271(a), (b), and/or (c) respectively of the '136 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

171. Judgment that Defendants MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd. have directly infringed, induced infringement of, and/or contributorily infringed, either literally or under the doctrine of equivalents, one or more claims of the Asserted Patents by filing ANDA No. 215976;

172. A declaration issued under 28 U.S.C. §§ 2201 and 2202 that if Defendants, its parent corporation, affiliates, subsidiaries, and each of its officers, agents, servants, employees, and those acting or attempting to act in privity or concert with them, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA Product prior to the expiration of the Asserted Patents, it will constitute an act of infringement of the Asserted Patents;

173. A preliminary and/or permanent injunction restraining and enjoining Defendants, and their affiliates, subsidiaries, and each of their officers, agents, servants, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the ANDA Product until the expiration of the last to expire of the Asserted Patents, inclusive of any extensions and additional periods of exclusivity to which Plaintiffs are or become entitled, or such later date as the Court may determine;

174. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 215976 shall be a date that is not earlier than the latest to expire of the ’225 patent, the ’335 patent, the ’980 patent, the ’630 patent, and the ’136 patent, inclusive of any extensions and additional periods of exclusivity to which Plaintiffs are or become entitled;

175. Damages or other monetary relief to Plaintiffs from Defendants for the infringement, inducement of infringement, or contributory infringement of the Asserted Patents if one or more defendant engages in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the ANDA Product prior to the latest expiration date of the ’225 patent, the ’335 patent, the ’980 patent, the ’630 patent, and the ’136 patent, inclusive of any extensions and additional periods of exclusivity to which Plaintiffs are or become entitled;

176. A declaration that this case is an exceptional case pursuant to 35 U.S.C. §285 and an award of attorney’s fees;

177. Plaintiffs’ costs and expenses in this action; and

178. Such other and further relief as the Court may deem just and proper.

Dated: July 29, 2021

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