IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION and ASTEX THERAPEUTICS LTD. Plaintiffs, v. FRESENIUS KABI USA, LLC and FRESENIUS KABI AG 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 Fresenius Kabi USA, LLC and Fresenius Kabi AG (collectively, "Fresenius" or "Defendants"). This action relates to Abbreviated New Drug Application ("ANDA") Nos. 214746 and 214771 (the "Fresenius ANDAs") 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 and KISQALI® FEMARA® CO-PACK (collectively, the "ANDA Products"), 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"), 9,193,732 ("the '732 patent), 9,416,136 ("the '136 patent"), 9,868,739 ("the '739 patent"), and 10,799,506 ("the '506 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® and the KISQALI® FEMARA® CO-PACK (collectively "KISQALI® Products") are such treatment options. Novartis markets and sells KISQALI® Products in this judicial district and throughout the United States.

B. Fresenius Kabi USA, LLC and Fresenius Kabi AG

6. Upon information and belief, Fresenius Kabi USA, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a registered agent for the service of process at Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808, and having a principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047. Upon information and belief, Fresenius Kabi USA, LLC is a wholly

owned subsidiary of Fresenius Kabi AG.

7. Upon information and belief, Fresenius Kabi AG is a corporation organized and existing under the laws of Germany, having a principal place of business at Else-Kröner-Straβe 1, 61352 Bad Homburg, Germany.

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 dated May 3, 2021 (the "First Fresenius Notice Letter"), Defendants notified Plaintiffs (i) that Fresenius had submitted to the FDA ANDA No. 214746, 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, the '732 patent, the '136 patent, the '739 patent, and the '506 patent, and (ii) that ANDA No. 214746 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, the '732 patent, the '136 patent, the '739 patent, and the '506 patent.

10. In a letter dated May 10, 2021 (the "Second Fresenius Notice Letter"), Defendants notified Plaintiffs (i) that Fresenius had submitted to the FDA ANDA No. 214771, seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a co-pack containing 200 mg ribociclib tablets and 2.5 mg letrozole 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, the ’732 patent, the ’136 patent, the ’739 patent, and the ’506 patent, and (ii) that ANDA No. 214771 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, the ’732 patent, the ’136 patent, the ’739 patent, and the ’506 patent.

11. Defendants have committed an act of infringement in this judicial district by filing the Fresenius ANDAs with the intent to make, use, sell, offer for sale, and/or import the ANDA Products in or into this judicial district prior to the expiration of the ’225 patent, the ’355 patent, the ’980 patent, the ’630 patent, the ’732 patent, the ’136 patent, the ’739 patent, and the ’506 patent, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

12. Upon information and belief, Fresenius Kabi AG acted in concert with and/or directed Fresenius Kabi USA, LLC in the preparation and submission of the Fresenius ANDAs and, if the Fresenius ANDAs are approved, will act in concert with and direct Fresenius Kabi USA, LLC to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the ANDA Products 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, the ’732 patent, the ’136 patent, the ’739 patent, and the ’506 patent.

13. Upon information and belief, Fresenius Kabi USA, LLC 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 Fresenius Kabi AG; 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. Upon information and belief, Fresenius Kabi AG 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 Fresenius Kabi USA, LLC; purposefully incorporated its wholly owned subsidiary Fresenius Kabi USA, LLC 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.

15. Fresenius Kabi USA, LLC has availed itself 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., Ferring Pharmaceuticals Inc. et al v. Fresenius Kabi USA, LLC et al*, Civ. Action No. 20-431 (D. Del. 2020); *Hoffmann-La Roche Inc. et al v. Fresenius Kabi USA, LLC et al*, Civ. Action No. 20-394 (D. Del. 2020); *Par Pharmaceutical, Inc. et al v. Fresenius Kabi USA, LLC*, Civ. Action No. 19-1985 (D. Del. 2019); *Millennium Pharmaceuticals, Inc. v. Fresenius Kabi USA, LLC*, Civ. Action No. 19-2252 (D. Del. 2019).

JURISDICTION AND VENUE

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

17. This Court has personal jurisdiction over Fresenius Kabi AG under Federal Rule of Civil Procedure 4(k)(2), because, upon information and belief, Fresenius Kabi AG is organized under the laws of Germany and the exercise of personal jurisdiction over Fresenius

Kabi AG is consistent with the United States Constitution and laws.

18. This Court has personal jurisdiction over Fresenius Kabi USA, LLC because Fresenius Kabi USA, LLC is a limited liability company organized and existing under Delaware law.

19. This Court also has personal jurisdiction over Fresenius Kabi USA, LLC and Fresenius Kabi AG 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 Fresenius ANDAs 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.

20. Upon information and belief, the effort to seek approval for the Fresenius ANDAs and to manufacture, import, market, and/or sell Defendants' ANDA Products upon approval has been a cooperative and joint enterprise and venture between Fresenius Kabi USA, LLC and Fresenius Kabi AG.

21. This Court also has personal jurisdiction over Fresenius Kabi USA, LLC and Fresenius Kabi AG because, upon information and belief, each such Defendant, independently or in concert, upon approval of the Fresenius ANDAs, will market, distribute, offer for sale, and/or sell Defendants' ANDA Products in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of the ANDA Products in the State of Delaware.

22. This Court also has personal jurisdiction over Fresenius Kabi USA, LLC and Fresenius Kabi AG because, upon information and belief, Defendants' ANDA Products, upon

approval of the Fresenius ANDAs, 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.

23. This Court also has personal jurisdiction over Fresenius Kabi USA, LLC and Fresenius Kabi AG because, upon information and belief, Defendants' affiliations with the State of Delaware, including Fresenius Kabi USA, LLC's organization in Delaware, Fresenius Kabi USA, LLC's availing itself, at Fresenius Kabi AG's direction, of the legal protections of the State of Delaware, and Fresenius Kabi AG's ownership of and actions in concert with Fresenius Kabi USA, LLC are sufficiently continuous and systematic as to render Defendants at home in this forum.

24. Upon information and belief, Fresenius Kabi USA, LLC and Fresenius Kabi AG operate as an integrated business with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products, including the ANDA Products, throughout the United States including in this judicial district.

25. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Fresenius Kabi USA, LLC and Fresenius Kabi AG.

26. Venue is proper in this Court because Fresenius Kabi USA, LLC is organized under the laws of the State of Delaware and therefore resides in this judicial district, and Fresenius Kabi AG 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®

27. 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**.

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

29. 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**.

30. 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.

31. 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**.

32. 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.

33. 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**.

34. 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.

35. Plaintiffs are the owners of the '732 patent, titled "Salt(s) of 7-Cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide and Processes of Making Thereof." The '732 patent was duly and legally issued on November 24, 2015. A true and correct copy of the '732 patent is attached hereto as **Exhibit E**.

36. The '732 patent generally claims succinate salt of 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide and a pharmaceutical composition comprising the same.

37. 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 F**.

38. 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.

39. Plaintiffs are the owners of the '739 patent, titled "Salt(s) of 7-Cyclopentyl-2-(5-

piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide and Processes of Making Thereof." The '739 patent was duly and legally issued on January 16, 2018. A true and correct copy of the '739 patent is attached hereto as **Exhibit G**.

40. The '739 patent generally claims a method of treating cancer which responds to inhibition of cyclin dependent kinases activity comprising administering to a subject in need a therapeutically effective amount of succinate salt of 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide.

41. Novartis Pharmaceuticals Corporation is the owner of the '506 patent, titled "Ribociclib Tablet." The '506 patent was duly and legally issued on October 13, 2020. A true and correct copy of the '506 patent is attached hereto as **Exhibit H**.

42. The '506 patent generally claims a coated pharmaceutical oral tablet comprising a tablet core and a coating, wherein the tablet core comprises ribociclib succinate.

43. 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.

44. Novartis is the holder of New Drug Application ("NDA") No. 209935 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of KISQALI® FEMARA® CO-PACK (ribociclib tablets and letrozole tablets). KISQALI® FEMARA® CO-PACK is currently indicated for use (i) in the treatment of pre/perimenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy and (ii) in the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy.

45. One or more claims of each of the Asserted Patents cover KISQALI®, KISQALI® FEMARA® CO-PACK, and/or the use of any of the foregoing.

46. The FDA's official publication of approved drugs (the "Orange Book") lists the Asserted Patents in connection with each of KISQALI® and KISQALI® FEMARA® CO-PACK.

INFRINGEMENT OF THE ASSERTED PATENTS

FIRST COUNT FOR PATENT INFRINGEMENT ('225 PATENT) (ANDA No. 214746)

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

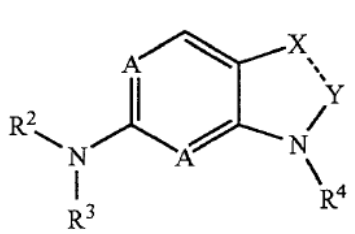
48. The '225 patent, entitled "Pyrrolopyrimidine Compounds and Their Uses," was issued on December 4, 2012. The '225 patent identifies Christopher Thomas Brain, Moo Je Sung, and Gebhard Thoma as inventors of the claimed subject matter. A true and correct copy of the '225 patent is attached hereto as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

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

50. 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.

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

52. 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.

53. 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.

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

55. 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.

56. The ’225 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations (“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).

57. Upon information and belief, Defendants submitted ANDA No. 214746 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.

58. Upon information and belief, Defendants' proposed generic ribociclib tablets that are the subject of ANDA No. 214746 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.

59. Plaintiffs received the First Fresenius Notice Letter dated May 3, 2021, purporting to include a Notice of Certification for ANDA No. 214746 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '225 patent. The First Fresenius Notice Letter did not allege non-infringement as to at least claim 1 of the '225 patent.

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

61. 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).

62. 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. 214746 seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '225 patent. Upon information and belief, the products described in ANDA No. 214746 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).

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

No. 214746 complained of herein were done by and for the benefit of Defendants.

64. Upon information and belief, Defendants had actual knowledge of the ’225 patent prior to the submission of ANDA No. 214746 to the FDA.

65. 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.

66. This action was commenced within 45 days of Plaintiffs’ receipt of the First Fresenius Notice Letter.

SECOND COUNT FOR PATENT INFRINGEMENT (’225 PATENT) (ANDA No. 214771)

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

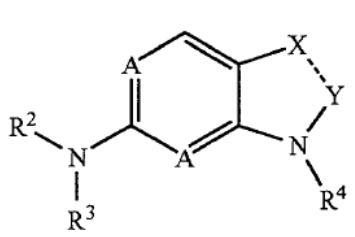
68. The ’225 patent, entitled “Pyrrolopyrimidine Compounds and Their Uses,” was issued on December 4, 2012. The ’225 patent identifies Christopher Thomas Brain, Moo Je Sung, and Gebhard Thoma as inventors of the claimed subject matter. A true and correct copy of the ’225 patent is attached hereto as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

69. Plaintiffs are the owners of the ’225 patent by virtue of assignment.

70. 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.

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

72. 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.

73. The FDA approved NDA No. 209935 on May 4, 2017, for KISQALI® FEMARA® CO-PACK (ribociclib tablets and letrozole 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.

74. The copackaged ribociclib tablets and letrozole tablets are marketed in the United States under the trademark KISQALI® FEMARA® CO-PACK.

75. FDA-approved KISQALI® FEMARA® CO-PACK comprises ribociclib succinate, in tablet form, copackaged with letrozole tablets. Ribociclib succinate is a pharmaceutically acceptable salt of ribociclib, a compound of Formula I according to claim 1 of the '225 patent.

76. The '225 patent is listed in the Orange Book for NDA No. 209935 for KISQALI® FEMARA® CO-PACK. At least one claim, including claim 1, of the '225 patent reads on FDA-approved KISQALI® FEMARA® CO-PACK (ribociclib tablets copackaged with letrozole tablets).

77. Upon information and belief, Defendants submitted ANDA No. 214771 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 a generic co-pack containing ribociclib tablets containing 200 mg ribociclib (upon information and belief in the form of ribociclib succinate) and 2.5 mg letrozole tablets in or into the United States, including Delaware.

78. Upon information and belief, Defendants' proposed generic co-pack product comprising generic ribociclib tablets that is the subject of ANDA No. 214771 contains 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 co-pack product comprising ribociclib tablets will therefore directly infringe at least claim 1 of the '225 patent.

79. Plaintiffs received the Second Fresenius Notice Letter dated May 10, 2021, purporting to include a Notice of Certification for ANDA No. 214771 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '225 patent. The Second Fresenius Notice Letter did not allege non-infringement as to at least claim 1 of the '225 patent.

80. Upon information and belief, Defendants seek FDA approval for generic versions of the ribociclib tablets (as part of their generic co-pack product) that are claimed in the '225 patent.

81. Upon information and belief, Defendants' generic co-pack product, 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).

82. 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. 214771 seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic co-pack product before the expiration date of the '225 patent. Upon information and belief, the co-pack product described in ANDA No. 214771 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).

83. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214771 complained of herein were done by and for the benefit of Defendants.

84. Upon information and belief, Defendants had actual knowledge of the '225 patent prior to the submission of ANDA No. 214771 to the FDA.

85. If Defendants' marketing and sale of their generic co-pack product, which comprises 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.

86. This action was commenced within 45 days of Plaintiffs' receipt of the Second Fresenius Notice Letter.

THIRD COUNT FOR PATENT INFRINGEMENT ('355 PATENT) (ANDA No. 214746)

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

88. 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**.

89. Plaintiffs are the owners of the '355 patent by virtue of assignment.

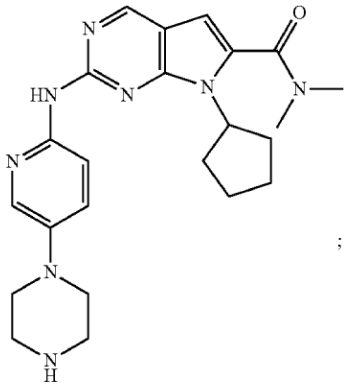
90. The '355 patent expires on February 19, 2031, which includes Patent Term Adjustment under 35 U.S.C. § 154, but excludes any Patent Term Extension under 35 U.S.C. § 156[1] and pediatric exclusivity.

91. 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

[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.

pharmaceutically acceptable salt thereof and a pharmaceutical composition comprising the same.

92. 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



;

or a pharmaceutically acceptable salt thereof.

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

94. 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).

95. Upon information and belief, Defendants submitted ANDA No. 214746 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.

96. Upon information and belief, Defendants' proposed generic ribociclib tablets that are the subject of ANDA No. 214746 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.

97. Plaintiffs received the First Fresenius Notice Letter dated May 3, 2021, purporting to include a Notice of Certification for ANDA No. 214746 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '355 patent. The First Fresenius Notice Letter did not allege non-infringement as to at least claim 1 of the '355 patent.

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

99. 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).

100. 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. 214746 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. 214746 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).

101. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214746 complained of herein were done by and for the benefit of Defendants.

102. Upon information and belief, Defendants had actual knowledge of the '355 patent prior to the submission of ANDA No. 214746 to the FDA.

103. 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.

104. This action was commenced within 45 days of Plaintiffs' receipt of the First Fresenius Notice Letter.

FOURTH COUNT FOR PATENT INFRINGEMENT ('355 PATENT) (ANDA No. 214771)

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

106. 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**.

107. Plaintiffs are the owners of the '355 patent by virtue of assignment.

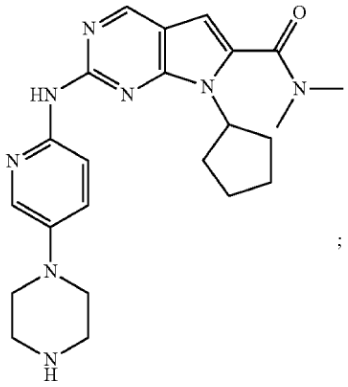
108. The '355 patent expires on February 19, 2031, which includes Patent Term Adjustment under 35 U.S.C. § 154, but excludes any Patent Term Extension under 35 U.S.C. § 156[2] and pediatric exclusivity.

109. The '355 patent generally claims 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-

[2] 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.

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.

110. 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



;

or a pharmaceutically acceptable salt thereof.

111. FDA-approved KISQALI® FEMARA® CO-PACK comprises ribociclib succinate, in tablet form, copackaged with letrozole tablets. Ribociclib succinate is a pharmaceutically acceptable salt of ribociclib, a compound of the formula according to claim 1 of the '355 patent.

112. The '355 patent is listed in the Orange Book for NDA No. 209935 for KISQALI® FEMARA® CO-PACK. At least one claim, including claim 1, of the '355 patent reads on FDA-approved KISQALI® FEMARA® CO-PACK (ribociclib tablets copackaged with letrozole tablets).

113. Upon information and belief, Defendants submitted ANDA No. 214771 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 a generic co-pack containing ribociclib tablets containing 200 mg ribociclib (upon information and belief in the

form of ribociclib succinate) and 2.5 mg letrozole tablets in or into the United States, including Delaware.

114. Upon information and belief, Defendants' proposed generic co-pack product, comprising generic ribociclib tablets, that is the subject of ANDA No. 214771 contains 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 of the formula in claim 1 of the '355 patent. Defendants' generic co-pack product comprising ribociclib tablets will therefore directly infringe at least claim 1 of the '355 patent.

115. Plaintiffs received the Second Fresenius Notice Letter dated May 10, 2021, purporting to include a Notice of Certification for ANDA No. 214771 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '355 patent. The Second Fresenius Notice Letter did not allege non-infringement as to at least claim 1 of the '355 patent.

116. Upon information and belief, Defendants seek FDA approval for generic versions of the ribociclib tablets (as part of their generic co-pack product) that are claimed in the '355 patent.

117. Upon information and belief, Defendants' generic co-pack product, 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).

118. 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. 214771 seeking approval to manufacture, use, import, offer

to sell or sell Defendants' generic co-pack product before the expiration date of the '355 patent. Upon information and belief, the co-pack product described in ANDA No. 214771 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).

119. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214771 complained of herein were done by and for the benefit of Defendants.

120. If Defendants' marketing and sale of their generic co-pack product, which comprises 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.

121. This action was commenced within 45 days of Plaintiffs' receipt of the Second Fresenius Notice Letter.

FIFTH COUNT FOR PATENT INFRINGEMENT ('980 PATENT) (ANDA No. 214746)

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

123. 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**.

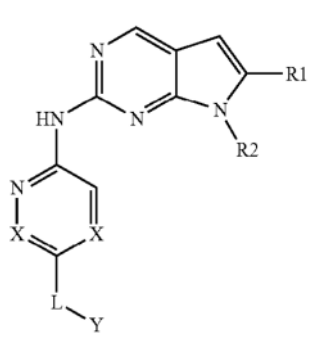
124. Plaintiffs are the owners of the '980 patent by virtue of assignment.

125. 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.

126. 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.

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



or a pharmaceutically acceptable salt thereof, wherein

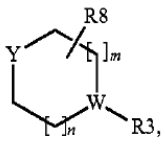
X is CR^9;

R^1 is $CONR^5R^6$, and R^5 and R^6 are $C_{1\text{-}8}$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, 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_{1-8}alkyl, C_{1-8}alkylC_{3-14}cycloalkyl, $C(O)C_{1-8}$alkylC_{3-14}cycloalkyl, C_{1-8}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_{1-8}alkyl, C_{3-14} cycloalkyl, a 3-14 membered cycloheteroalkyl group, a C_{6-14} aryl group, a 5-14 membered heteroaryl group, alkoxy, C(O)H, C(NH)OH, $C(NH)OCH_3$, $C(O)C_{1-3}$alkyl, C_{1-8}alkylNH_2, and C_{1-6}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_{1-8}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.

128. 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.

129. 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).

130. Upon information and belief, Defendants submitted ANDA No. 214746 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.

131. Upon information and belief, Defendants' proposed generic ribociclib tablets that are the subject of ANDA No. 214746 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.

132. Plaintiffs received the First Fresenius Notice Letter dated May 3, 2021, purporting to include a Notice of Certification for ANDA No. 214746 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '980 patent. The First Fresenius Notice Letter did not allege non-infringement as to claim 1 of the '980 patent.

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

134. 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).

135. 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. 214746 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. 214746 would infringe, either literally or under the doctrine of equivalents, at least one claim including at least claim 1 of the '980 patent under 35 U.S.C. § 271(e)(2)(A).

136. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214746 complained of herein were done by and for the benefit of Defendants.

137. Upon information and belief, Defendants had actual knowledge of the '980 patent prior to the submission of ANDA No. 214746 to the FDA.

138. 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.

139. This action was commenced within 45 days of Plaintiffs' receipt of the First Fresenius Notice Letter.

SIXTH COUNT FOR PATENT INFRINGEMENT ('980 PATENT) (ANDA No. 214771)

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

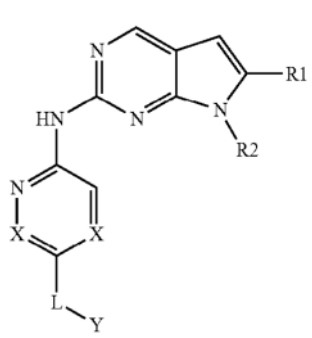
141. The '980 patent, entitled "Pyrrolopyrimidine Compounds and Their Uses," was issued on April 1, 2014. The '980 patent identifies Gilbert Ebai Besong, Christopher Thomas Brain, Clinton Alan Brooks, Miles Stuart Congreve, Claudio Dagostin, Guo He, Ying Hou, Steven Howard, Yue Li, Yipin Lu, Paul Neil 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**.

142. Plaintiffs are the owners of the '980 patent by virtue of assignment.

143. 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.

144. 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.

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



or a pharmaceutically acceptable salt thereof, wherein

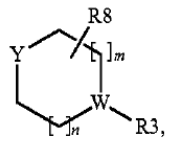
X is CR^9;

R^1 is $CONR^5R^6$, and R^5 and R^6 are $C_{1\text{-}8}$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, 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_{1-8}alkyl, C_{1-8}alkylC_{3-14}cycloalkyl, $C(O)C_{1-8}$alkylC_{3-14}cycloalkyl, C_{1-8}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_{1-8}alkyl, C_{3-14} cycloalkyl, a 3-14 membered cycloheteroalkyl group, a C_{6-14} aryl group, a 5-14 membered heteroaryl group, alkoxy, C(O)H, C(NH)OH, $C(NH)OCH_3$, $C(O)C_{1-3}$alkyl, C_{1-8}alkylNH_2, and C_{1-6}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_{1-8}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.

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

147. The ’980 patent is listed in the Orange Book for NDA No. 209935 for KISQALI® FEMARA® CO-PACK. At least one claim, including claim 1, of the ’980 patent reads on FDA-

approved KISQALI® FEMARA® CO-PACK (ribociclib tablets copackaged with letrozole tablets).

148. Upon information and belief, Defendants submitted ANDA No. 214771 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 a generic co-pack containing ribociclib tablets containing 200 mg ribociclib (upon information and belief in the form of ribociclib succinate) and 2.5 mg letrozole tablets in or into the United States, including Delaware.

149. Upon information and belief, Defendants' proposed generic co-pack product, comprising generic ribociclib tablets, that is the subject of ANDA No. 214771 contains 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 co-pack product comprising generic ribociclib tablets will therefore directly infringe at least claim 1 of the '980 patent.

150. Plaintiffs received the Second Fresenius Notice Letter dated May 10, 2021, purporting to include a Notice of Certification for ANDA No. 214771 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '980 patent. The Second Fresenius Notice Letter did not allege non-infringement as to at least claim 1 of the '980 patent.

151. Upon information and belief, Defendants seek FDA approval for generic versions of the ribociclib tablets (as part of their generic co-pack product) that are claimed in the '980 patent.

152. Upon information and belief, Defendants' generic co-pack products, 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).

153. 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. 214771 seeking approval to manufacture, use, import, offer to sell or sell Defendants’ generic co-pack products before the expiration date of the ’980 patent. Upon information and belief, the co-pack products described in ANDA No. 214771 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).

154. Upon information and belief, Defendants’ actions relating to Defendants’ ANDA No. 214771 complained of herein were done by and for the benefit of Defendants.

155. If Defendants’ marketing and sale of their generic co-pack product, which comprises 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.

156. This action was commenced within 45 days of Plaintiffs’ receipt of the Second Fresenius Notice Letter.

SEVENTH COUNT FOR PATENT INFRINGEMENT
(’630 PATENT) (ANDA No. 214746)

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

158. 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**.

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

160. 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.

161. 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.

162. 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.

163. 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).

164. Plaintiffs received the First Fresenius Notice Letter dated May 3, 2021, purporting to include a Notice of Certification for ANDA No. 214746 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the ’630 patent. The First Fresenius Notice Letter did not allege that it would not indirectly infringe at least claim 1 of the ’630 patent.

165. 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.

166. 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).

167. 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.

168. Upon information and belief, Defendants filed ANDA No. 214746 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. 214746, 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.

169. Upon information and belief, if the FDA approves ANDA No. 214746,

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).

170. Upon information and belief, if the FDA approves ANDA No. 214746, Defendants will sell or offer to sell their 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 products 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).

171. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214746 complained of herein were done by and for the benefit of Defendants.

172. Upon information and belief, Defendants had actual knowledge of the '630 patent prior to the submission of ANDA No. 214746 to the FDA.

173. 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.

174. This action was commenced within 45 days of Plaintiffs' receipt of the First Fresenius Notice Letter.

EIGHTH COUNT FOR PATENT INFRINGEMENT ('630 PATENT) (ANDA No. 214771)

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

176. 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**.

177. Plaintiffs are the owners of the '630 patent by virtue of assignment.

178. 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.

179. 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.

180. 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.

181. The '630 patent is listed in the Orange Book for NDA No. 209935 for KISQALI® FEMARA® CO-PACK. At least one claim, including claim 1, of the '630 patent reads on FDA-

approved KISQALI® FEMARA® CO-PACK (ribociclib tablets copackaged with letrozole tablets).

182. Plaintiffs received the Second Fresenius Notice Letter dated May 10, 2021, purporting to include a Notice of Certification for ANDA No. 214771 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '630 patent. The Second Fresenius Notice Letter did not allege that it would not indirectly infringe at least claim 1 of the '630 patent.

183. Upon information and belief, Defendants' generic products, 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).

184. 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® FEMARA® CO-PACK 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.

185. Upon information and belief, Defendants filed ANDA No. 214771 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. 214771, 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.

186. Upon information and belief, if the FDA approves ANDA No. 214771, 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).

187. Upon information and belief, if the FDA approves ANDA No. 214771, Defendants will sell or offer to sell their 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).

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

No. 214771 complained of herein were done by and for the benefit of Defendants.

189. 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.

190. This action was commenced within 45 days of Plaintiffs' receipt of the Second Fresenius Notice Letter.

NINTH COUNT FOR PATENT INFRINGEMENT ('732 PATENT) (ANDA No. 214746)

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

192. The '732 patent, entitled "Salt(s) of 7-Cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide and Processes of Making Thereof," was issued on November 24, 2015. The '732 patent identifies John Vincent Calienni, Guang-Pei Chen, Baoqing Gong, Prasad Koteswara Kapa, and Vishal Saxena as inventors of the claimed subject matter. A true and correct copy of the '732 patent is attached hereto as **Exhibit E**.

193. Plaintiffs are the owners of the '732 patent by virtue of assignment.

194. The '732 patent expires on November 9, 2031, excluding any pediatric exclusivity.

195. The '732 patent generally claims succinate salts of 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide and a pharmaceutical composition comprising a therapeutically effective amount of such a salt.

196. Claim 9 recites: A pharmaceutical composition comprising (a) a therapeutically effective amount of a salt according to any of claims 1-8; and (b) at least one pharmaceutically

acceptable carrier, diluent, vehicle or excipient.

197. FDA-approved ribociclib tablets in KISQALI® (ribociclib) comprise ribociclib succinate, which is a pharmaceutically acceptable salt of ribociclib, i.e., 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide recited in the claims of the '732 patent, and also contain at least one pharmaceutically acceptable carrier, diluent, vehicle or excipient recited in claim 9 of the '732 patent.

198. The '732 patent is listed in the Orange Book for NDA No. 209092 for KISQALI®. At least one claim, including claim 9, of the '732 patent reads on FDA-approved KISQALI® (ribociclib tablets).

199. Upon information and belief, Defendants' proposed generic ribociclib tablets that are the subject of ANDA No. 214746 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 the claims of the '732 patent, and also contain at least one pharmaceutically acceptable carrier, diluent, vehicle or excipient recited in claim 9 of the '732 patent. Defendants' generic ribociclib tablets will therefore directly infringe at least claim 9 of the '732 patent.

200. Plaintiffs received the First Fresenius Notice Letter dated May 3, 2021, purporting to include a Notice of Certification for ANDA No. 214746 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '732 patent. The First Fresenius Notice Letter did not allege non-infringement as to at least claim 9 of the '732 patent.

201. Upon information and belief, Defendants seek FDA approval for generic versions

of the ribociclib tablets that contain the salts and pharmaceutically acceptable carriers, diluents, vehicles or excipients claimed in at least claim 9 of the ’732 patent.

202. Upon information and belief, Defendants intend to engage in the commercial manufacture, marketing, importation, use, offer to sell and/or sale of Defendants’ generic ribociclib tablets in the United States, including in this judicial district, upon receiving FDA approval of ANDA No. 214746.

203. 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 9, of the ’732 patent under 35 U.S.C. § 271(a).

204. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim, including claim 9, of the ’732 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 214746 seeking approval to manufacture, use, import, offer to sell or sell Defendants’ generic ribociclib tablets before the expiration date of the ’732 patent. Upon information and belief, the products described in ANDA No. 214746 would infringe, either literally or under the doctrine of equivalents, at least one claim, including claim 9, of the ’732 patent under 35 U.S.C. § 271(e)(2)(A).

205. Upon information and belief, Defendants’ actions relating to Defendants’ ANDA No. 214746 complained of herein were done by and for the benefit of Defendants.

206. Upon information and belief, Defendants had actual knowledge of the ’732 patent prior to the submission of ANDA No. 214746 to the FDA.

207. If Defendants’ marketing and sale of generic ribociclib succinate tablets prior to expiration of the ’732 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.

208. This action was commenced within 45 days of Plaintiffs' receipt of the First Fresenius Notice Letter.

TENTH COUNT FOR PATENT INFRINGEMENT ('732 PATENT) (ANDA No. 214771)

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

210. The '732 patent, entitled "Salt(s) of 7-Cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide and Processes of Making Thereof," was issued on November 24, 2015. The '732 patent identifies John Vincent Calienni, Guang-Pei Chen, Baoqing Gong, Prasad Koteswara Kapa, and Vishal Saxena as inventors of the claimed subject matter. A true and correct copy of the '732 patent is attached hereto as **Exhibit E**.

211. Plaintiffs are the owners of the '732 patent by virtue of assignment.

212. The '732 patent expires on November 9, 2031, excluding any pediatric exclusivity.

213. The '732 patent generally claims succinate salts of 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide and a pharmaceutical composition comprising a therapeutically effective amount of such a salt.

214. Claim 9 recites: A pharmaceutical composition comprising (a) a therapeutically effective amount of a salt according to any of claims 1-8; and (b) at least one pharmaceutically acceptable carrier, diluent, vehicle or excipient.

215. FDA-approved KISQALI® FEMARA® CO-PACK comprises ribociclib succinate tablets copackaged with letrozole tablets. Ribociclib succinate is a pharmaceutically acceptable

salt of ribociclib, i.e., 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide recited in the claims of the '732 patent, and also contain at least one pharmaceutically acceptable carrier, diluent, vehicle or excipient recited in claim 9 of the '732 patent.

216. The '732 patent is listed in the Orange Book for NDA No. 209935 for KISQALI® FEMARA® CO-PACK. At least one claim, including claim 9, of the '732 patent, reads on FDA-approved KISQALI® FEMARA® CO-PACK (ribociclib tablets and letrozole tablets).

217. Upon information and belief, Defendants' proposed generic copack product comprising generic ribociclib tablets that is the subject of ANDA No. 214771 contain ribociclib succinate, which is a pharmaceutically acceptable salt of ribociclib i.e., 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide recited in the claims of the '732 patent, and also contain at least one pharmaceutically acceptable carrier, diluent, vehicle or excipient recited in claim 9 of the '732 patent. Defendants' generic ribociclib tablets will therefore directly infringe at least claim 9 of the '732 patent.

218. Plaintiffs received the Second Fresenius Notice Letter dated May 10, 2021, purporting to include a Notice of Certification for ANDA No. 214771 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '732 patent. The Second Fresenius Notice Letter did not allege non-infringement as to at least claim 9 of the '732 patent.

219. Upon information and belief, Defendants seek FDA approval for generic versions of the ribociclib tablets that contain the salts and pharmaceutically acceptable carriers, diluents, vehicles or excipients claimed in at least claim 9 of the '732 patent.

220. Upon information and belief, Defendants intend to engage in the commercial manufacture, marketing, importation, use, offer to sell and/or sale of Defendants' generic ribociclib tablets in the United States, including in this judicial district, upon receiving FDA approval of ANDA No. 214771.

221. Upon information and belief, Defendants' generic co-pack products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim, including claim 9 ,of the '732 patent under 35 U.S.C. § 271(a).

222. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim, including claim 9, of the '732 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 214771 seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic co-pack product before the expiration date of the '732 patent. Upon information and belief, the co-pack products described in ANDA No. 214771 would infringe, either literally or under the doctrine of equivalents, at least one claim, including claim 9, of the '732 patent under 35 U.S.C. § 271(e)(2)(A).

223. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214771 complained of herein were done by and for the benefit of Defendants.

224. If Defendants' marketing and sale of their generic co-pack product, which comprises ribociclib succinate tablets, prior to expiration of the '732 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.

225. This action was commenced within 45 days of Plaintiffs' receipt of the Second Fresenius Notice Letter.

ELEVENTH COUNT FOR PATENT INFRINGEMENT ('136 PATENT) (ANDA No. 214746)

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

227. 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 F**.

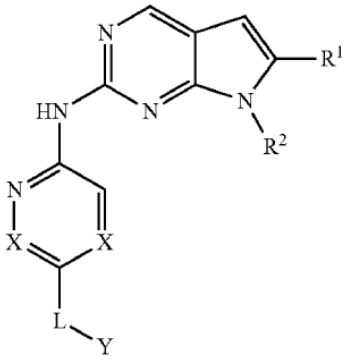
228. Plaintiffs are the owners of the '136 patent by virtue of assignment.

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

230. 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.

231. 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



,

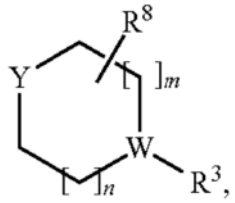
wherein X is CR^9;

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

232. 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).

233. Plaintiffs received the First Fresenius Notice Letter dated May 3, 2021, purporting to include a Notice of Certification for ANDA No. 214746 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the ’136 patent. The First Fresenius Notice Letter did not allege that it would not indirectly infringe as to at least claim 1 of the ’136 patent.

234. 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.

235. 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).

236. 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.

237. Upon information and belief, Defendants filed ANDA No. 214746 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. 214746, 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.

238. Upon information and belief, if the FDA approves ANDA No. 214746, 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).

239. Upon information and belief, if the FDA approves ANDA No. 214746, Defendants will sell or offer to sell their 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 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).

240. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214746 complained of herein were done by and for the benefit of Defendants.

241. Upon information and belief, Defendants had actual knowledge of the '136 patent prior to the submission of ANDA No. 214746 to the FDA.

242. 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.

243. This action was commenced within 45 days of Plaintiffs' receipt of the First Fresenius Notice Letter.

TWELFTH COUNT FOR PATENT INFRINGEMENT ('136 PATENT) (ANDA No. 214771)

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

245. 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 F**.

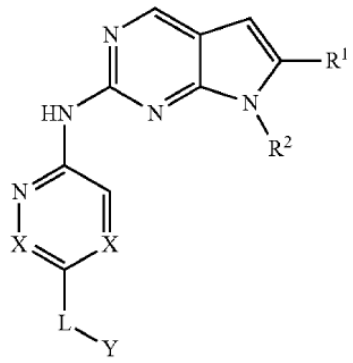
246. Plaintiffs are the owners of the '136 patent by virtue of assignment.

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

248. 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.

249. 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;

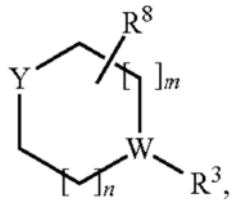
R^1 is $CONR^5R^6$, and R^5 and R^6 are C_{1-8}alkyl;

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, 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.

250. The ’136 patent is listed in the Orange Book for NDA No. 209935 for KISQALI® FEMARA® CO-PACK. At least one claim, including claim 1, of the ’136 patent reads on FDA-approved KISQALI® FEMARA® CO-PACK (ribociclib tablets copackaged with letrozole

tablets).

251. Plaintiffs received the Second Fresenius Notice Letter dated May 10, 2021, purporting to include a Notice of Certification for ANDA No. 214771 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '136 patent. The Second Fresenius Notice Letter did not allege that it did not indirectly infringe at least claim 1 of the '136 patent.

252. Upon information and belief, Defendants seek FDA approval for methods of use of generic versions of the ribociclib tablets (as part of their generic co-pack product) that are claimed in the '136 patent.

253. Upon information and belief, Defendants' generic co-pack products, 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).

254. Ribociclib is a compound of formula I as recited in claim 1 of the '136 patent. FDA-approved KISQALI® FEMARA® CO-PACK 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.

255. Upon information and belief, Defendants filed ANDA No. 214771 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. 214771, physicians, health care providers, and/or patients will use Defendants' generic co-pack products 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.

256. Upon information and belief, if the FDA approves ANDA No. 214771, Defendants know and intend that physicians, health care providers, and/or patients will prescribe, administer, and/or use Defendants' generic co-pack products 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).

257. Upon information and belief, if the FDA approves ANDA No. 214771, Defendants will sell or offer to sell their generic co-pack products 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).

258. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214771 complained of herein were done by and for the benefit of Defendants.

259. Upon information and belief, Defendants had actual knowledge of the '136 patent prior to the submission of ANDA No. 214771 to the FDA.

260. If Defendants' marketing and sale of their generic co-pack product, which comprises 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.

261. This action was commenced within 45 days of Plaintiffs' receipt of the Second Fresenius Notice Letter.

THIRTEENTH COUNT FOR PATENT INFRINGEMENT ('739 PATENT) (ANDA No. 214746)

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

263. The '739 patent, entitled "Salt(s) of 7-Cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide and Processes of Making Thereof," was issued on January 16, 2018. The '739 patent identifies John Vincent Calienni, Guang-Pei Chen, Baoqing Gong, Prasad Koteswara Kapa, and Vishal Saxena as inventors of the claimed subject matter. A true and correct copy of the '739 patent is attached hereto as **Exhibit G**.

264. Plaintiffs are the owners of the '739 patent by virtue of assignment.

265. The '739 patent expires on November 9, 2031, excluding any pediatric exclusivity.

266. The ’739 patent generally claims a method of treating cancer which responds to inhibition of cyclin dependent kinase activity comprising administering to a subject in need a therapeutically effective amount of succinate salt of 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide.

267. Claim 9 recites: The method of any one of claims 1-8 [drawn to methods of treating cancer which responds to inhibition of cyclin dependent kinases activity comprising administering to a subject in need a therapeutically effective amount of succinate salt of 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide characterized by initial or post-DVS XRPD illustrated in FIG. 2, initial or post-DVS DSC illustrated in FIG. 3, initial or post-DVS TGA illustrated in FIG. 4, initial or post-DVS XRPD illustrated in FIG. 6], wherein the cancer is breast cancer, genitourinary cancer, lung cancer, gastrointestinal cancer, epidermoid cancer, melanoma, ovarian cancer, neuroblastoma, head and/or neck cancer, hyperplasias, larynx cancer, lymphatic system cancer, bone cancer, epidermas cancer, hematopoietic cancer, myeloma, thyroid follicular cancer, a tumor of mesenchymal origin, a tumor of the central or peripheral nervous system, seminoma, teratocarcinoma, xeroderma pigmentosum, and Kaposi's sarcoma.

268. The ’739 patent is listed in the Orange Book for NDA No. 209092 for KISQALI®. At least one claim, including claim 9, of the ’739 patent reads on FDA-approved KISQALI® (ribociclib tablets).

269. Plaintiffs received the First Fresenius Notice Letter dated May 3, 2021, purporting to include a Notice of Certification for ANDA No. 214746 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the ’739 patent. The First Fresenius Notice Letter did not allege it did

not indirectly infringe at least claim 9 of the ’739 patent.

270. Upon information and belief, Defendants seek FDA approval for methods of use of generic versions of the ribociclib tablets, which comprises ribociclib succinate, a pharmaceutically acceptable salt of ribociclib, that are claimed in the ’739 patent.

271. Upon information and belief, Defendants’ generic products, if approved and marketed in the United States, will infringe, either literally or under the doctrine of equivalents, at least one claim, including claim 9, of the ’739 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

272. Ribociclib succinate is a succinate salt of 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide as recited in claims 1-8 upon which claim 9 of the ’739 patent depends. FDA-approved 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.

273. Upon information and belief, Defendants filed ANDA No. 214746 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. 214746, 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 9, of the ’739 patent.

274. Upon information and belief, if the FDA approves ANDA No. 214746,

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 9, of the '739 patent with the requisite intent under 35 U.S.C. § 271(b).

275. Upon information and belief, if the FDA approves ANDA No. 214746, Defendants will sell or offer to sell their 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 9, of the '739 patent, and wherein generic ribociclib succinate 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 9, of the '739 patent under 35 U.S.C. § 271(c).

276. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214746 complained of herein were done by and for the benefit of Defendants.

277. Upon information and belief, Defendants had actual knowledge of the '739 patent prior to the submission of ANDA No. 214746 to the FDA.

278. If Defendants' marketing and sale of generic ribociclib succinate tablets prior to expiration of the '739 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.

279. This action was commenced within 45 days of Plaintiffs' receipt of the First Fresenius Notice Letter.

FOURTEENTH COUNT FOR PATENT INFRINGEMENT ('739 PATENT) (ANDA No. 214771)

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

281. The '739 patent, entitled "Salt(s) of 7-Cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide and Processes of Making Thereof," was issued on January 16, 2018. The '739 patent identifies John Vincent Calienni, Guang-Pei Chen, Baoqing Gong, Prasad Koteswara Kapa, and Vishal Saxena as inventors of the claimed subject matter. A true and correct copy of the '739 patent is attached hereto as **Exhibit G**.

282. Plaintiffs are the owners of the '739 patent by virtue of assignment.

283. The '739 patent expires on November 9, 2031, excluding any pediatric exclusivity.

284. The '739 patent generally claims a method of treating cancer which responds to inhibition of cyclin dependent kinase activity comprising administering to a subject in need a therapeutically effective amount of succinate salt of 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide.

285. Claim 9 recites: The method of any one of claims 1-8 [drawn to methods of treating cancer which responds to inhibition of cyclin dependent kinases activity comprising administering to a subject in need a therapeutically effective amount of succinate salt of 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic

acid dimethylamide characterized by initial or post-DVS XRPD illustrated in FIG. 2, initial or post-DVS DSC illustrated in FIG. 3, initial or post-DVS TGA illustrated in FIG. 4, initial or post-DVS XRPD illustrated in FIG. 6], wherein the cancer is breast cancer, genitourinary cancer, lung cancer, gastrointestinal cancer, epidermoid cancer, melanoma, ovarian cancer, neuroblastoma, head and/or neck cancer, hyperplasias, larynx cancer, lymphatic system cancer, bone cancer, epidermas cancer, hematopoietic cancer, myeloma, thyroid follicular cancer, a tumor of mesenchymal origin, a tumor of the central or peripheral nervous system, seminoma, teratocarcinoma, xeroderma pigmentosum, and Kaposi's sarcoma.

286. The ’739 patent is listed in the Orange Book for NDA No. 209935 for KISQALI® FEMARA® CO-PACK. At least one claim, including claim 9, of the ’739 patent reads on FDA-approved KISQALI® FEMARA® CO-PACK (ribociclib tablets copackaged with letrozole tablets).

287. Plaintiffs received the Second Fresenius Notice Letter dated May 10, 2021, purporting to include a Notice of Certification for ANDA No. 214771 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the ’739 patent. The Second Fresenius Notice Letter did not allege it did not indirectly infringe at least claim 9 of the ’739 patent.

288. Upon information and belief, Defendants seek FDA approval for methods of use of generic versions of the ribociclib tablets, which comprises ribociclib succinate, a pharmaceutically acceptable salt of ribociclib, (as part of their generic co-pack product) that are claimed in the ’739 patent.

289. Upon information and belief, Defendants’ generic co-pack products, if approved and marketed in the United States, will infringe, either literally or under the doctrine of

equivalents, at least one claim, including claim 9, of the ’739 patent under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

290. Ribociclib succinate is a succinate salt of 7-cyclopentyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-7H-pyrrolo[2,3-d]pyrimidine-6-carboxylic acid dimethylamide as recited in claims 1-8 upon which claim 9 of the ’739 patent depends. FDA-approved 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.

291. Upon information and belief, Defendants filed ANDA No. 214771 seeking authorization to commercially manufacture, use, import, offer to sell or sell Defendants’ generic co-pack products in the United States. Upon information and belief, if the FDA approves ANDA No. 214771, physicians, health care providers, and/or patients will use Defendants’ generic co-pack products 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 9, of the ’739 patent.

292. Upon information and belief, if the FDA approves ANDA No. 214771, 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 9, of the ’739 patent with the requisite intent under 35 U.S.C. § 271(b)..

293. Upon information and belief, if the FDA approves ANDA No. 214771,

Defendants will sell or offer to sell their 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 Defendant's provided instructions and/or label, wherein such use will directly infringe at least one claim, including claim 9, of the '739 patent, and wherein generic ribociclib succinate 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 9, of the '739 patent under 35 U.S.C. § 271(c).

294. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 214771 complained of herein were done by and for the benefit of Defendants.

295. Upon information and belief, Defendants had actual knowledge of the '739 patent prior to the submission of ANDA No. 214771 to the FDA.

296. If Defendants' marketing and sale of their generic co-pack product, which comprises ribociclib succinate tablets, prior to expiration of the '739 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.

297. This action was commenced within 45 days of Plaintiffs' receipt of the Second Fresenius Notice Letter.

FIFTEENTH COUNT FOR PATENT INFRINGEMENT ('506 PATENT) (ANDA No. 214746)

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

299. The ’506 patent, entitled “Ribociclib Tablet,” was issued on October 13, 2020. The ’506 patent identifies Bindhumadhavan Gururajan, Arnaud Grandeury, and Rui Costa as inventors of the claimed subject matter. A true and correct copy of the ’506 patent is attached hereto as **Exhibit H**.

300. Novartis Pharmaceuticals Corporation is the owner of the ’506 patent by virtue of assignment.

301. The ’506 patent expires on April 14, 2036, excluding any pediatric exclusivity.

302. The ’506 patent generally claims a coated pharmaceutical oral tablet comprising a tablet core and a coating, wherein the tablet core comprises ribociclib succinate.

303. Claim 1 recites: A coated pharmaceutical oral tablet comprising tablet core and a coating, wherein the tablet core comprises at least 40% of ribociclib succinate (w/w), the coating comprises 45.52% polyvinyl alcohol (PVA), 20% talc, 2% lecithin, and 0.48% xanthan gum, and lacks hydroxypropyl methylcellulose (HPMC), and the tablet releases at least 75% of the ribociclib or its salt after 45 minutes when tested with the rotating basket at 100 rpm with 900 ml of dissolution media pH 2 or pH 4.5, at 37° C., according to United States Pharmacopeia (USP)<711>.

304. FDA-approved KISQALI® comprises ribociclib succinate, which is contained in tablets according to claim 1 of the ’506 patent.

305. The ’506 patent is listed in the Orange Book for NDA No. 209092 for KISQALI®. At least one claim, including claim 1, of the ’506 patent reads on FDA-approved KISQALI® (ribociclib tablets).

306. Upon information and belief, Defendants’ proposed generic ribociclib tablets that

are the subject of ANDA No. 214746 contain ribociclib succinate, the core and coating materials, and the release characteristics contained in the tablets according to claim 1 of the '506 patent. Defendants' generic ribociclib succinate tablets will therefore directly infringe at least claim 1 of the '506 patent.

307. Plaintiffs received the First Fresenius Notice Letter dated May 3, 2021, purporting to include a Notice of Certification for ANDA No. 214746 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '506 patent. The First Fresenius Notice Letter did not allege non-infringement as to at least claim 1 of the '506 patent.

308. Upon information and belief, Defendants seek FDA approval for generic versions of the ribociclib tablets that are claimed in the '506 patent.

309. Upon information and belief, Defendants intend to engage in the commercial manufacture, marketing, importation, use, offer to sell and/or sale of Defendants' generic ribociclib tablets in the United States, including in this judicial district, upon receiving FDA approval of ANDA No. 214746.

310. 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 '506 patent under 35 U.S.C. § 271(a).

311. 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 '506 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 214746 seeking approval to manufacture, use, import, offer to sell or sell Defendants' generic ribociclib tablets before the expiration date of the '506 patent. Upon information and belief, the products described in ANDA No. 214746 would infringe, either

literally or under the doctrine of equivalents, at least one claim, including claim 1, of the ’506 patent under 35 U.S.C. § 271(e)(2)(A).

312. Upon information and belief, Defendants’ actions relating to Defendants’ ANDA No. 214746 complained of herein were done by and for the benefit of Defendants.

313. Upon information and belief, Defendants had actual knowledge of the ’506 patent prior to the submission of ANDA No. 214746 to the FDA.

314. If Defendants’ marketing and sale of generic ribociclib tablets prior to expiration of the ’506 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.

315. This action was commenced within 45 days of Plaintiffs’ receipt of the First Fresenius Notice Letter.

SIXTEENTH COUNT FOR PATENT INFRINGEMENT (’506 PATENT) (ANDA No. 214771)

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

317. The ’506 patent, entitled “Ribociclib Tablet,” was issued on October 13, 2020. The ’506 patent identifies Bindhumadhavan Gururajan, Arnaud Grandeury, and Rui Costa as inventors of the claimed subject matter. A true and correct copy of the ’506 patent is attached hereto as **Exhibit H**.

318. Novartis Pharmaceuticals Corporation is the owner of the ’506 patent by virtue of assignment.

319. The ’506 patent expires on April 14, 2036, excluding any pediatric exclusivity.

320. The ’506 patent generally claims a coated pharmaceutical oral tablet comprising a tablet core and a coating, wherein the tablet core comprises ribociclib succinate.

321. Claim 1 recites: A coated pharmaceutical oral tablet comprising tablet core and a coating, wherein the tablet core comprises at least 40% of ribociclib succinate (w/w), the coating comprises 45.52% polyvinyl alcohol (PVA), 20% talc, 2% lecithin, and 0.48% xanthan gum, and lacks hydroxypropyl methylcellulose (HPMC), and the tablet releases at least 75% of the ribociclib or its salt after 45 minutes when tested with the rotating basket at 100 rpm with 900 ml of dissolution media pH 2 or pH 4.5, at 37° C., according to United States Pharmacopeia (USP)<711>.

322. FDA-approved KISQALI® FEMARA® CO-PACK comprises ribociclib succinate, which is contained in the tablets according to claim 1 of the ’506 patent.

323. The ’506 patent is listed in the Orange Book for NDA No. 209935 for KISQALI® FEMARA® CO-PACK. At least one claim, including claim 1, of the ’506 patent reads on FDA-approved KISQALI® FEMARA® CO-PACK (ribociclib tablets copackaged with letrozole tablets).

324. Upon information and belief, Defendants’ proposed generic co-pack product, comprising generic ribociclib tablets, that is the subject of ANDA No. 214771 contains ribociclib succinate, the core and coating materials, and the release characteristics contained in the tablets according to claim 1 of the ’506 patent. Defendants’ generic co-pack product comprising ribociclib tablets will therefore directly infringe at least claim 1 of the ’506 patent.

325. Plaintiffs received the Second Fresenius Notice Letter dated May 10, 2021, purporting to include a Notice of Certification for ANDA No. 214771 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the ’506 patent. The Second Fresenius Notice Letter did not allege non-infringement as to at least claim 1 of the ’506 patent

326. Upon information and belief, Defendants seek FDA approval for generic versions of the ribociclib tablets, which comprises ribociclib succinate, a pharmaceutically acceptable salt of ribociclib, (as part of their generic co-pack product) that are claimed in the ’506 patent.

327. Upon information and belief, Defendants intend to engage in the commercial manufacture, marketing, importation, use, offer to sell and/or sale of Defendants’ generic ribociclib tablets (as part of their generic co-pack product) in the United States, including in this judicial district, upon receiving FDA approval of ANDA No. 214771.

328. Upon information and belief, Defendants’ generic co-pack product, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim, including claim 1, of the ’506 patent under 35 U.S.C. § 271(a).

329. 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 ’506 patent by submitting, or causing to be submitted, to the FDA, ANDA No. 214771 seeking approval to manufacture, use, import, offer to sell or sell Defendants’ generic co-pack products before the expiration date of the ’506 patent. Upon information and belief, the co-pack products described in ANDA No. 214771 would infringe, either literally or under the doctrine of equivalents, at least one claim, including claim 1, of the ’506 patent under 35 U.S.C. § 271(e)(2)(A).

330. Upon information and belief, Defendants’ actions relating to Defendants’ ANDA No. 214771 complained of herein were done by and for the benefit of Defendants.

331. Upon information and belief, Defendants had actual knowledge of the ’506 patent prior to the submission of ANDA No. 214771 to the FDA.

332. If Defendants’ marketing and sale of their generic co-pack product, which

comprises ribociclib tablets, prior to expiration of the ’506 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.

333. This action was commenced within 45 days of Plaintiffs’ receipt of the Second Fresenius Notice Letter.

PRAYER FOR RELIEF

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

334. Judgment that Defendants Fresenius Kabi USA, LLC and Fresenius Kabi AG have directly infringed, induced infringement of, and/or contributorily infringed one or more claims of the Asserted Patents by filing ANDA No. 214746 and ANDA No. 214771;

335. A 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 Products 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;

336. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 214746 and ANDA No. 214771 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, the ’732 patent, the ’136 patent, the ’739 patent, and the ’506 patent, inclusive of any extensions and additional periods of exclusivity to which Plaintiffs are or become entitled;

337. 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 Products prior to the latest expiration date of the '225 patent, the '335 patent, the '980 patent, the '630 patent, the '732 patent, the '136 patent, the '739 patent, and the '506 patent, inclusive of any extensions and additional periods of exclusivity to which Plaintiffs are or become entitled;

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

339. Plaintiffs' costs and expenses in this action; and

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

Dated: June 17, 2021

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