IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT

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

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against defendants MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd. (collectively, "MSN" or "Defendants"). This action relates to Abbreviated New Drug Application ("ANDA") Nos. 215975 and 215976 (the "MSN 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. 8,962,630 ("the '630 patent") and 9,416,136 ("the '136 patent") (collectively, "the Asserted Patents").

PARTIES

A. Novartis Pharmaceuticals Corporation and Astex Therapeutics Ltd.

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

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

4. Plaintiffs own all rights in the Asserted Patents.

5. Plaintiffs are engaged in the business of creating, developing, and bringing to market revolutionary drug therapies to benefit patients against serious diseases, including treatments for breast cancer. KISQALI® 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. MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd.

6. Upon information and belief, MSN Pharmaceuticals Inc. is a corporation incorporated and existing under the laws of the State of Delaware, having a registered agent for the service of process at United States Corporation Agents, Inc., 651 N. Broad Street, Suite 201, Middletown, Delaware 19709, and having a principal place of business at 20 Duke Rd, Piscataway, NJ 08854-3714. Upon information and belief, MSN Pharmaceuticals Inc. is a wholly owned subsidiary of MSN Laboratories Pvt. Ltd.

7. Upon information and belief, MSN Laboratories Pvt. Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at MSN House, Plot No.: C-24, Industrial Estate, Sanathnagar, Hyderabad, 500018, Telangana, India.

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

DEFENDANTS' INFRINGING ACTS

9. In a letter dated April 7, 2023 (the "April 2023 Kisqali Letter"), Defendants notified Plaintiffs (i) that MSN had submitted to the FDA ANDA No. 215975, 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 '630 patent and the '136 patent, and (ii) that ANDA No. 215975 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '630 patent and the '136 patent.

10. In a letter dated April 7, 2023 (the "April 2023 Kisqali Femara Copack Letter"), Defendants notified Plaintiffs (i) that MSN had submitted to the FDA ANDA No. 215976, seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of 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 '630 patent and the '136 patent, and (ii) that ANDA No. 215976 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '630 patent and the '136 patent.

11. Defendants have committed an act of infringement in this judicial district by filing the MSN 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 '630 patent and the '136 patent, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis, a Delaware corporation.

12. Upon information and belief, MSN Laboratories Pvt. Ltd. acted in concert with and/or directed MSN Pharmaceuticals Inc. in the preparation and submission of the MSN ANDAs

and, if the MSN ANDAs are approved, will act in concert with and direct MSN Pharmaceuticals Inc. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the ANDA Products in or into the United States, including Delaware, prior to the expiration of the '630 patent and the '136 patent.

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

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

15. MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd. have availed themselves of the legal protections of the State of Delaware by, among other things, conceding jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g., Novartis Pharmaceuticals Corp. et al. v. MSN Pharmaceuticals Inc. et al.*, Civ. Action No. 21-981 (D. Del. 2021); *Novartis Pharmaceuticals Corp. et al. v. MSN Pharmaceuticals Inc. et al.*, Civ. Action No. 21-1102 (D. Del. 2021); *Vanda Pharmaceuticals Inc.*

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

JURISDICTION AND VENUE

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

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

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

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

21. This Court also has personal jurisdiction over MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd. because, upon information and belief, each such Defendant, independently

or in concert, upon approval of the MSN ANDA, will market, distribute, offer for sale, and/or sell Defendants' ANDA 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 MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd. because, upon information and belief, Defendants' ANDA Products, upon approval of the MSN 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 MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd. because, upon information and belief, Defendants' affiliations with the State of Delaware, including MSN Pharmaceuticals Inc.'s incorporation in Delaware, MSN Pharmaceuticals Inc.'s availing itself, at MSN Laboratories Pvt. Ltd.'s direction, of the legal protections of the State of Delaware, and MSN Laboratories Pvt. Ltd.'s ownership of and actions in concert with MSN Pharmaceuticals Inc. are sufficiently continuous and systematic as to render Defendants at home in this forum.

24. Upon information and belief, MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd. operate as an integrated business with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products, including the ANDA 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 MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd.

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

THE PATENTS-IN-SUIT AND KISQALI®

27. 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 A**.

28. 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.

29. 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 B**.

30. 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.

31. 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.

32. 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.

33. 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.

34. 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 ('630 PATENT) (ANDA NO. 215975)

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

36. 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 A**.

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

38. 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.

39. 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.

40. 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.

41. 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).

42. Plaintiffs received the April 2023 Kisqali Letter dated April 7, 2023, purporting to include a Notice of Certification for ANDA No. 215975 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the ’630 patent. The April 2023 Kisqali Letter did not allege that it would not indirectly infringe at least claim 1 of the ’630 patent.

43. 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.

44. 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).

45. 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.

46. Upon information and belief, Defendants filed ANDA No. 215975 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. 215975, 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.

47. Upon information and belief, if the FDA approves ANDA No. 215975, 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).

48. Upon information and belief, if the FDA approves ANDA No. 215975, 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).

49. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 215975 complained of herein were done by and for the benefit of Defendants.

50. Upon information and belief, Defendants had actual knowledge of the '630 patent prior to the submission of ANDA No. 215975 to the FDA.

51. 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.

52. This action was commenced within 45 days of Plaintiffs' receipt of the April 2023 Kisqali Letter.

SECOND COUNT FOR PATENT INFRINGEMENT ('630 PATENT) (ANDA NO. 215976)

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

54. 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 A**.

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

56. 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.

57. 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.

58. 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.

59. 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).

60. Plaintiffs received the April 2023 Kisqali Femara Copack Letter dated April 7, 2023, purporting to include a Notice of Certification for ANDA No. 215976 under 21 U.S.C. §

355(j)(2)(B) and 21 C.F.R. § 314.95 as to the '630 patent. The April 2023 Kisqali Femara Copack Letter did not allege that it would not indirectly infringe at least claim 1 of the '630 patent.

61. 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).

62. 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.

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

64. Upon information and belief, if the FDA approves ANDA No. 215976, Defendants

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

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

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

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

68. 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.

69. This action was commenced within 45 days of Plaintiffs' receipt of the April 2023 Kisqali Femara Copack Letter.

THIRD COUNT FOR PATENT INFRINGEMENT ('136 PATENT) (ANDA NO. 215976)

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

71. 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 B**.

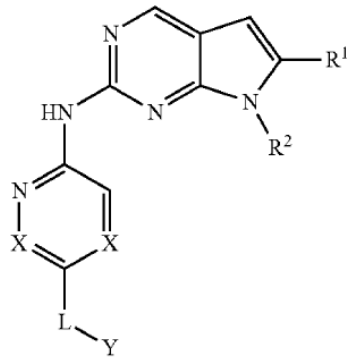
72. Plaintiffs are the owners of the '136 patent by virtue of assignment.

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

74. 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.

75. 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



,

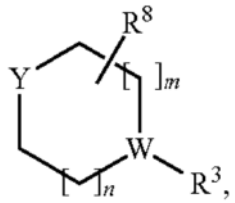
wherein X is CR^9;

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.

76. 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).

77. Plaintiffs received the April 2023 Kisqali Letter dated April 7, 2023, purporting to include a Notice of Certification for ANDA No. 215975 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the ’136 patent. The April 2023 Kisqali Letter did not allege that it would not indirectly infringe as to at least claim 1 of the ’136 patent.

78. 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.

79. 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).

80. 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.

81. Upon information and belief, Defendants filed ANDA No. 215975 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. 215975, 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.

82. Upon information and belief, if the FDA approves ANDA No. 215975, 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).

83. Upon information and belief, if the FDA approves ANDA No. 215975, 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).

84. Upon information and belief, Defendants’ actions relating to Defendants’ ANDA No. 215975 complained of herein were done by and for the benefit of Defendants.

85. Upon information and belief, Defendants had actual knowledge of the ’136 patent prior to the submission of ANDA No. 215975 to the FDA.

86. 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.

87. This action was commenced within 45 days of Plaintiffs’ receipt of the April 2023 Kisqali Letter.

FOURTH COUNT FOR PATENT INFRINGEMENT
(’136 PATENT) (ANDA NO. 215976)

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

89. 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 B**.

90. Plaintiffs are the owners of the ’136 patent by virtue of assignment.

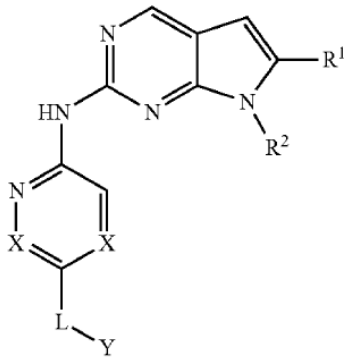
91. The ’136 patent expires on August 20, 2029, excluding any pediatric exclusivity.

92. 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.

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

I



,

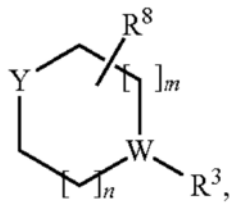
wherein X is CR^9;

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

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

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

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



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

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

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

R^9 is H or halogen;

m and n are independently 0-2; and

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

94. 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).

95. Plaintiffs received the April 2023 Kisqali Femara Copack Letter dated April 7, 2023, purporting to include a Notice of Certification for ANDA No. 215976 under 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 as to the ’136 patent. The April 2023 Kisqali Femara Copack Letter did not allege that it did not indirectly infringe at least claim 1 of the ’136 patent.

96. 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.

97. 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).

98. 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.

99. Upon information and belief, Defendants filed ANDA No. 215976 seeking authorization to commercially manufacture, use, import, offer to sell or sell Defendants' generic ribociclib tablets in the United States. Upon information and belief, if the FDA approves ANDA No. 215976, physicians, health care providers, and/or patients will use Defendants' generic 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.

100. Upon information and belief, if the FDA approves ANDA No. 215976, Defendants know and intend that physicians, health care providers, and/or patients will prescribe, administer, and/or use Defendants' generic 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).

101. Upon information and belief, if the FDA approves ANDA No. 215976, 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).

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

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

104. 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.

105. This action was commenced within 45 days of Plaintiffs’ receipt of the April 2023 Kisqali Femara Copack Letter.

PRAYER FOR RELIEF

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

106. Judgment that Defendants MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd. have directly infringed, induced infringement of, and/or contributorily infringed one or more claims of the Asserted Patents by filing ANDA No. 215975 and ANDA No. 215976;

107. 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;

108. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 215975 and ANDA No. 215976 shall be a date that is not earlier than the latest to expire of the ’630 patent and the ’136 patent, inclusive of any extensions and additional periods of exclusivity to which Plaintiffs are or become entitled;

109. 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 ’630 patent and the ’136 patent, inclusive of any extensions and additional periods of exclusivity to which Plaintiffs are or become entitled;

110. A declaration that this case is an exceptional case pursuant to 35 U.S.C. § 285 and

an award of attorney's fees;

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

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

Dated: May 19, 2023

OF COUNSEL:

Jill K. MacAlpine, Ph.D.
Matthew J. Hlinka
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Ave., NW
Washington, DC 20001
Phone: (202) 408-4000
jill.macalpine@finnegan.com
matthew.hlinka@finnegan.com

John D. Livingstone
M. David Weingarten, Ph.D.
Megan L. Meyers
Shannon M. Patrick
Candace C. Walther
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
271 17th St. NW, Suite 1400
Atlanta, GA 30306
Phone: (404) 653-6400
john.livingstone@finnegan.com
david.weingarten@finnegan.com
megan.meyers@finnegan.com
shannon.patrick@finnegan.com
candace.walther@finnegan.com

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
T: (302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com

Attorneys for Plaintiffs Novartis Pharmaceuticals Corporation and Astex Therapeutics Ltd.