IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| PFIZER INC., GLOBAL BLOOD THERAPEUTICS, INC. and PF PRISM IMB B.V., | ) | |
| Plaintiffs, | ) | |
| v. | ) | C.A. No._____ |
| MSN LABORATORIES PRIVATE LTD. and MSN PHARMACEUTICALS INC., | ) | |
| Defendants. | ) | |

**COMPLAINT**

Plaintiffs Pfizer Inc. ("Pfizer"), Global Blood Therapeutics, Inc. ("GBT"), and PF PRISM IMB B.V. ("PF PRISM") (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against defendants MSN Laboratories Private Ltd. ("MSN Laboratories") and MSN Pharmaceuticals Inc. ("MSN Pharmaceuticals") (collectively, "MSN" or "Defendants"), allege as follows:

**NATURE OF THE ACTION**

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, arising from MSN's submission of Abbreviated New Drug Application ("ANDA") No. 219094 to the United States Food and Drug Administration ("FDA"), seeking approval to market generic versions of Plaintiffs' OXBRYTA® (voxelotor) tablets before the expiration of U.S. Patent No. 9,447,071 ("the '071 patent"), U.S. Patent No. 10,493,035 ("the '035 patent"), U.S. Patent No. 10,722,502 ("the '502 patent"), U.S. Patent No. 11,020,382 ("the '382 patent"), and U.S. Patent No. 11,452,720 ("the '720 patent") (collectively, "the patents-in-suit").

## THE PARTIES

2. Plaintiff Pfizer is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 66 Hudson Boulevard East, New York, NY 10001.

3. Plaintiff GBT is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 181 Oyster Point Blvd, South San Francisco, CA 94080. GBT is a wholly owned subsidiary of Pfizer.

4. Plaintiff PF PRISM is a private limited liability company (*besloten venootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJessel, the Netherlands. Pfizer is the ultimate parent of PF PRISM.

5. Upon information and belief, Defendant MSN Laboratories is a company 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.

6. Upon information and belief, Defendant MSN Pharmaceuticals is a corporation organized and existing under the laws of Delaware, having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854.

7. Upon information and belief, MSN Pharmaceuticals is a wholly-owned subsidiary of MSN Laboratories.

8. Upon information and belief, MSN Laboratories and MSN Pharmaceuticals are generic pharmaceutical companies that, in coordination with each other or at the direction of MSN Laboratories, develop, manufacture, market, and distribute generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

## THE PATENTS-IN-SUIT

9. On September 20, 2016, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '071 patent, entitled "Crystalline Polymorphs of the Free Base of 2-Hydroxy-6-((2- (1-isopropyl-1H-pyrazol-5-yl)-pyridin-3-yl)methoxy)benzaldehyde." The '071 patent is assigned to GBT. PF PRISM is the exclusive licensee of the '071 patent. A copy of the '071 patent is attached to this Complaint as Exhibit A.

10. On December 3, 2019, the USPTO duly and legally issued the '035 patent, entitled "Tablets Comprising 2-Hydroxy-6-((2- (1-isopropyl-1H-pyrazol-5-yl)-pyridin-3-yl)methoxy)benzaldehyde." The '035 patent is assigned to GBT. PF PRISM is the exclusive licensee of the '035 patent. A copy of the '035 patent is attached to this Complaint as Exhibit B.

11. On July 28, 2020, the USPTO duly and legally issued the '502 patent, entitled "Crystalline Polymorphs of the Free Base of 2-Hydroxy-6-((2- (1-isopropyl-1H-pyrazol-5-yl)-pyridin-3-yl)methoxy)benzaldehyde." The '502 patent is assigned to GBT. PF PRISM is the exclusive licensee of the '502 patent. A copy of the '502 patent is attached to this Complaint as Exhibit C.

12. On June 1, 2021, the USPTO duly and legally issued the '382 patent, entitled "Dosing Regimens for 2-Hydroxy-6-((2- (1-isopropyl-1H-pyrazol-5-yl)-pyridin-3-yl)methoxy)benzaldehyde." The '382 patent is assigned to GBT. PF PRISM is the exclusive licensee of the '382 patent. A copy of the '382 patent is attached to this Complaint as Exhibit D.

13. On September 27, 2022, the USPTO duly and legally issued the '720 patent, entitled "Crystalline Polymorphs of the Free Base of 2-Hydroxy-6-((2- (1-isopropyl-1H-pyrazol-5-yl)-pyridin-3-yl)methoxy)benzaldehyde." The '720 patent is assigned to GBT. PF

PRISM is the exclusive licensee of the '720 patent. A copy of the '720 patent is attached to this Complaint as Exhibit E.

**OXBRYTA®**

14. GBT holds approved New Drug Application No. 213137 for voxelotor tablets (trade name OXBRYTA®) for the treatment of sickle cell disease in adults and pediatric patients 4 years of age and older.

15. Pursuant to 21 U.S.C. § 355(c)(2), and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to OXBRYTA®.

**THE MSN ANDA**

16. Upon information and belief, MSN Laboratories prepared and submitted, through MSN Pharmaceuticals, ANDA No. 219094 (the "MSN ANDA") to the FDA in accordance with 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of voxelotor tablets ("MSN's ANDA Product") before the expiration of the patents-in-suit.

17. Upon information and belief, MSN Laboratories acted in concert with or directed MSN Pharmaceuticals to prepare and submit the MSN ANDA.

18. Upon information and belief, MSN's ANDA Product is a generic copy of OXBRYTA®.

19. Upon information and belief, the MSN ANDA refers to and relies upon GBT's New Drug Application No. 213137 and purports to contain data on the bioequivalence of MSN's ANDA Product to OXBRYTA®.

20. By a letter to GBT and its parent company Pfizer dated January 24, 2024 ("MSN's Paragraph IV Notice Letter"), MSN stated that the MSN ANDA contained certifications, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that no valid and enforceable

claim of the patents-in-suit will be infringed by the manufacture, use, or sale of MSN's ANDA Product (the "Paragraph IV Certifications"). MSN's Paragraph IV Notice Letter included a statement purporting to allege the factual and legal bases for the Paragraph IV Certifications.

21. MSN's Paragraph IV Notice Letter includes very limited information about the nature and form of MSN's ANDA Product, including little to no information regarding how MSN's ANDA Product is manufactured, the formulation of MSN's ANDA Product, or the form of voxelotor present in MSN's ANDA Product and during the manufacture thereof.

22. MSN's Paragraph IV Notice Letters purported to offer confidential access to the MSN ANDA ("Offer of Confidential Access" or "OCA") on terms and conditions set by MSN. The OCA did not grant access to the Drug Master File ("DMF") that supports the MSN ANDA, or samples of MSN's ANDA Product. MSN requested that GBT and Pfizer accept the terms of the OCA before receiving access to the MSN ANDA.

23. Since receiving MSN's Paragraph IV Notice Letter, Plaintiffs have attempted to negotiate with MSN to obtain a copy of the MSN ANDA under reasonable terms. These negotiations were unsuccessful.

24. Upon information and belief, if the FDA approves the MSN ANDA, MSN will manufacture, distribute, import, offer for sale and/or sell MSN's ANDA Product throughout the United States, including within the State of Delaware.

25. This action is being filed within 45 days of GBT and Pfizer's receipt of MSN's Paragraph IV Notice Letter.

## JURISDICTION AND VENUE

26. This case arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

27. This Court has personal jurisdiction over MSN Laboratories because, inter alia, it has purposefully availed itself of the privileges and benefits of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, MSN Laboratories is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, MSN Laboratories directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and Delaware. By continuously placing its products into the stream of commerce for distribution and consumption in Delaware, MSN Laboratories's contacts with Delaware have been systematic and continuous, and this judicial district is a likely destination of MSN's ANDA Product.

28. Upon information and belief, MSN Laboratories is the holder of the MSN ANDA.

29. Upon information and belief, MSN Laboratories acted in concert with or directed MSN Pharmaceuticals to prepare and submit the MSN ANDA, with the intention of receiving a significant financial benefit from the FDA's approval of the MSN ANDA. *See, e.g.*, https://msnpi.com/ (last accessed Mar. 8, 2024) ("[MSN Pharmaceuticals] was established in the year 2014. Finished Dosage form facility was built in 2018. . . . [MSN Pharmaceuticals] is a fully owned subsidiary of the MSN group of companies. [MSN Pharmaceuticals] develops and manufacture products for MSN group. . . .").

30. This Court has personal jurisdiction over MSN Pharmaceuticals because its affiliations with the State of Delaware, including by virtue of its incorporation in Delaware, are so continuous and systematic that MSN Pharmaceuticals resides in Delaware.

31. This Court also has personal jurisdiction over MSN Pharmaceuticals because, inter alia, it has purposefully availed itself of the privileges and benefits of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and

belief, MSN Pharmaceuticals is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, MSN Pharmaceuticals directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and Delaware. By continuously placing its products into the stream of commerce for distribution and consumption in Delaware, MSN Pharmaceuticals's contacts with the State of Delaware have been systematic and continuous, and this judicial district is a likely destination of MSN's ANDA Product.

32. Upon information and belief, MSN Pharmaceuticals acted in concert with or at the direction of MSN Laboratories to prepare and submit the MSN ANDA, with the intention of receiving a significant financial benefit from marketing and distribution of MSN's ANDA Product throughout the United States, including in Delaware. *See, e.g.*, https://msnpi.com/ (last accessed Mar. 8, 2024) ("[MSN Pharmaceuticals] was established in the year 2014. Finished Dosage form facility was built in 2018. . . . [MSN Pharmaceuticals] is a fully owned subsidiary of the MSN group of companies. [MSN Pharmaceuticals] develops and manufacture products for MSN group. . . .").

33. Upon information and belief, MSN Laboratories and MSN Pharmaceuticals have thus been, and continue to be, agents of each other and/or operate in concert with respect to the drafting, submission, approval, and maintenance of the MSN ANDA.

34. Upon information and belief, MSN Laboratories and MSN Pharmaceuticals are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to MSN's ANDA Product.

35. This Court also has personal jurisdiction over MSN Laboratories and MSN Pharmaceuticals because they have availed themselves of the legal protections of the State of Delaware by previously consenting to personal jurisdiction in this judicial district and by asserting counterclaims against plaintiffs. *See, e.g.*, *Allergan Holdings Unlimited Co. v.*

*MSN Lab'ys Priv. Ltd.*, C.A. No. 23-794 (D. Del.); *Actelion Pharms. US, Inc. v. MSN Lab'ys Priv. Ltd.*, C.A. No. 23-731 (D. Del.); *Celgene Corp. v. MSN Lab'ys Priv. Ltd.*, C.A. No. 23-699 (D. Del.); *Astellas Pharma Inc. v. MSN Pharms. Inc.*, C.A. No. 23-689 (D. Del.); *Abbvie Inc. v. Alkem Lab'ys Ltd.*, C.A. No. 22-1423 (D. Del.).

36. For these and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over MSN.

37. Venue is proper in this Court for MSN Laboratories under 28 U.S.C. § 1391 because, upon information and belief, MSN Laboratories is not a resident of the United States and may thus be sued in any judicial district.

38. Venue is proper in this Court for MSN Pharmaceuticals under 28 U.S.C. §§ 1391 and 1400(b) because MSN Pharmaceuticals is a corporation organized and existing under the laws of Delaware.

**COUNT I**
**(Infringement of the '071 Patent)**

39. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

40. Defendants have infringed one or more claims of the '071 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining the MSN ANDA, by which Defendants seek approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of MSN's ANDA Product before the expiration of the '071 patent.

41. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '071 patent would infringe one or more claims of the '071 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

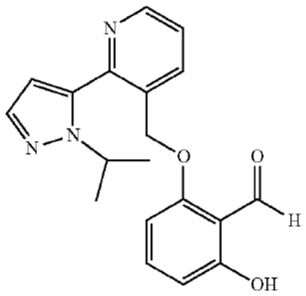
42. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's

ANDA Product into the United States, during the term of the '071 patent would induce and/or contribute to the infringement of one or more claims of the '071 patent under 35 U.S.C. §§ 271(b) and/or (c).

43. For example, claim 1 of the '071 patent recites:

A crystalline ansolvate of Compound 1:

Compound 1




wherein the crystalline ansolvate is characterized by at least one X-ray powder diffraction peak (Cu Kα radiation) selected from 13.37°, 14.37°, 19.95° and 23.92° 2θ (each ±0.2° 2θ).

44. Upon information and belief, MSN's ANDA Product will contain a crystalline ansolvate of Compound 1 wherein the crystalline ansolvate is characterized by at least one X-ray powder diffraction peak (Cu Kα radiation) selected from 13.37°, 14.37°, 19.95°, and 23.92° 2θ (each ±0.2° 2θ).

45. Upon information and belief, Defendants have acted with full knowledge of the '071 patent and without a reasonable basis for believing that they would not be liable for infringement of the '071 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product with its proposed labeling immediately and imminently upon approval of the MSN ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '071 patent.

46. Upon information and belief, if the FDA approves the MSN ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '071 patent, and will do so immediately and imminently upon approval.

47. Upon information and belief, Defendants know that MSN's ANDA Product is especially made or adapted for use in infringing the '071 patent, and that MSN's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '071 patent immediately and imminently upon approval of the MSN ANDA.

48. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '071 patent.

49. Plaintiffs have no adequate remedy at law.

50. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

**COUNT II**
**(Declaratory Judgment of Infringement of the '071 Patent)**

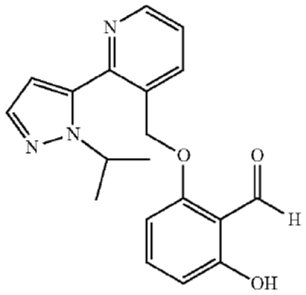
51. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

52. There is a substantial and immediate controversy between Plaintiffs and MSN concerning the '071 patent. Plaintiffs are entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that MSN will infringe, actively induce infringement of, and/or contribute to the infringement of the '071 patent upon approval of the MSN ANDA.

53. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '071 patent would infringe one or more claims of the '071 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

54. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '071 patent would induce and/or contribute to the infringement of one or more claims of the '071 patent under 35 U.S.C. §§ 271(b) and/or (c).

55. For example, claim 1 of the '071 patent recites:

> A crystalline ansolvate of Compound 1:
>
> Compound 1
>
> 
> 
>
> wherein the crystalline ansolvate is characterized by at least one X-ray powder diffraction peak (Cu Kα radiation) selected from 13.37°, 14.37°, 19.95° and 23.92° 2θ (each ±0.2° 2θ).

56. Upon information and belief, MSN's ANDA Product will contain a crystalline ansolvate of Compound 1 wherein the crystalline ansolvate is characterized by at least one X-ray powder diffraction peak (Cu Kα radiation) selected from 13.37°, 14.37°, 19.95°, and 23.92° 2θ (each ±0.2° 2θ).

57. Upon information and belief, Defendants have acted with full knowledge of the '071 patent and without a reasonable basis for believing that they would not be liable for infringement of the '071 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product with its proposed labeling immediately and imminently upon approval of the MSN ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '071 patent.

58. Upon information and belief, if the FDA approves the MSN ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '071 patent, and will do so immediately and imminently upon approval.

59. Upon information and belief, Defendants know that MSN's ANDA Product is especially made or adapted for use in infringing the '071 patent, and that MSN's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '071 patent immediately and imminently upon approval of the MSN ANDA.

60. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '071 patent.

61. Plaintiffs have no adequate remedy at law.

62. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

63. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of MSN's ANDA Product with its proposed labeling will infringe the '071 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

## COUNT III
**(Infringement of the '035 Patent)**

64. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

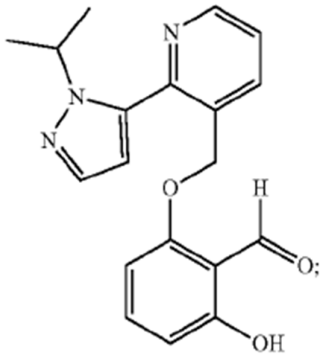
65. Defendants have infringed one or more claims of the '035 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining the MSN ANDA, by which Defendants seek approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of MSN's ANDA Product before the expiration of the '035 patent.

66. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '035 patent would infringe one

or more claims of the '035 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

67. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '035 patent would induce and/or contribute to the infringement of one or more claims of the '035 patent under 35 U.S.C. §§ 271(b) and/or (c).

68. For example, claim 1 of the '035 patent recites:

> A tablet comprising:
> (i) about 50% to about 70% by weight of Compound 1 of formula:
>
> 
> 
>
> (ii) about 30 % to about 40 % by weight of microcrystalline cellulose;
> (iii) about 0.25% to about 3% by weight of croscarmellose sodium;
> (iv) about 1% to about 5% by weight of magnesium stearate;
> (v) about 0.5% to about 2.5% of sodium lauryl sulfate; and
> (vi) about 0.25% to about 5% by weight of colloidal silicon dioxide;
> wherein the percentage by weight is relative to the total weight of the tablet.

69. Upon information and belief, MSN's ANDA Product will be a tablet comprising (i) about 50% to about 70% by weight of Compound 1; (ii) about 30 % to about 40 % by weight of microcrystalline cellulose; (iii) about 0.25% to about 3% by weight of croscarmellose sodium; (iv) about 1% to about 5% by weight of magnesium stearate; (v) about 0.5% to about 2.5% of sodium lauryl sulfate; and (vi) about 0.25% to about 5% by weight of colloidal silicon dioxide; wherein the percentage by weight is relative to the total weight of the tablet.

70. Upon information and belief, Defendants have acted with full knowledge of the '035 patent and without a reasonable basis for believing that they would not be liable for infringement of the '035 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product with its proposed labeling immediately and imminently upon approval of the MSN ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '035 patent.

71. Upon information and belief, if the FDA approves the MSN ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '035 patent, and will do so immediately and imminently upon approval.

72. Upon information and belief, Defendants know that MSN's ANDA Product is especially made or adapted for use in infringing the '035 patent, and that MSN's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '035 patent immediately and imminently upon approval of the MSN ANDA.

73. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '035 patent.

74. Plaintiffs have no adequate remedy at law.

75. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

**COUNT IV**
**(Declaratory Judgment of Infringement of the '035 Patent)**

76. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

77. There is a substantial and immediate controversy between Plaintiffs and MSN concerning the '035 patent. Plaintiffs are entitled to a declaratory judgment under 28 U.S.C.

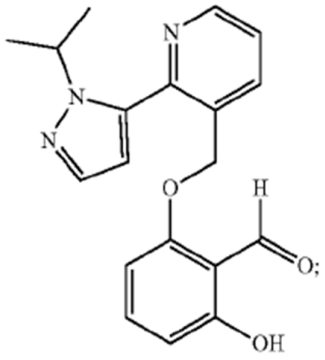
§§ 2201 and 2202 that MSN will infringe, actively induce infringement of, and/or contribute to the infringement of the '035 patent upon approval of the MSN ANDA.

78. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '035 patent would infringe one or more claims of the '035 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

79. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '035 patent would induce and/or contribute to the infringement of one or more claims of the '035 patent under 35 U.S.C. §§ 271(b) and/or (c).

80. For example, claim 1 of the '035 patent recites:

> A tablet comprising:
> (i) about 50% to about 70% by weight of Compound 1 of formula:




> (ii) about 30 % to about 40 % by weight of microcrystalline cellulose;
> (iii) about 0.25% to about 3% by weight of croscarmellose sodium;
> (iv) about 1% to about 5% by weight of magnesium stearate;
> (v) about 0.5% to about 2.5% of sodium lauryl sulfate; and
> (vi) about 0.25% to about 5% by weight of colloidal silicon dioxide;
> wherein the percentage by weight is relative to the total weight of the tablet.

81. Upon information and belief, MSN's ANDA Product will be a tablet comprising (i) about 50% to about 70% by weight of Compound 1; (ii) about 30 % to about 40 % by weight

of microcrystalline cellulose; (iii) about 0.25% to about 3% by weight of croscarmellose sodium; (iv) about 1% to about 5% by weight of magnesium stearate; (v) about 0.5% to about 2.5% of sodium lauryl sulfate; and (vi) about 0.25% to about 5% by weight of colloidal silicon dioxide; wherein the percentage by weight is relative to the total weight of the tablet.

82. Upon information and belief, Defendants have acted with full knowledge of the '035 patent and without a reasonable basis for believing that they would not be liable for infringement of the '035 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product with its proposed labeling immediately and imminently upon approval of the MSN ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '035 patent.

83. Upon information and belief, if the FDA approves the MSN ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '035 patent, and will do so immediately and imminently upon approval.

84. Upon information and belief, Defendants know that MSN's ANDA Product is especially made or adapted for use in infringing the '035 patent, and that MSN's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '035 patent immediately and imminently upon approval of the MSN ANDA.

85. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '035 patent.

86. Plaintiffs have no adequate remedy at law.

87. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

88. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of MSN's ANDA Product with its proposed labeling will infringe the '035 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

**COUNT V**
**(Infringement of the '502 Patent)**

89. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

90. Defendants have infringed one or more claims of the '502 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining the MSN ANDA, by which Defendants seek approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of MSN's ANDA Product before the expiration of the '502 patent.

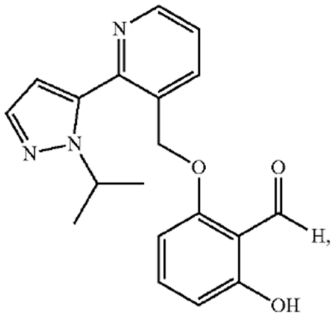
91. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '502 patent would infringe one or more claims of the '502 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

92. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '502 patent would induce and/or contribute to the infringement of one or more claims of the '502 patent under 35 U.S.C. §§ 271(b) and/or (c).

93. For example, claim 1 of the '502 patent recites:

A composition comprising a crystalline ansolvate of Compound 1:

Compound 1



characterized by X-ray powder diffraction peaks (Cu Kα radiation) at 13.37°, 14.37°, 19.95° and 23.92° 2θ (each ±0.2° 2θ), wherein the composition is substantially free of other ansolvate polymorphs of Compound 1.

94. Upon information and belief, MSN's ANDA Product will contain a composition comprising a crystalline ansolvate of Compound 1, characterized by X-ray powder diffraction peaks (Cu Kα radiation) at 13.37°, 14.37°, 19.95°, and 23.92° 2θ (each ±0.2° 2θ), wherein the composition is substantially free of other ansolvate polymorphs of Compound 1.

95. Upon information and belief, Defendants have acted with full knowledge of the '502 patent and without a reasonable basis for believing that they would not be liable for infringement of the '502 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product with its proposed labeling immediately and imminently upon approval of the MSN ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '502 patent.

96. Upon information and belief, if the FDA approves the MSN ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '502 patent, and will do so immediately and imminently upon approval.

97. Upon information and belief, Defendants know that MSN's ANDA Product is especially made or adapted for use in infringing the '502 patent, and that MSN's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief,

Defendants plan and intend to, and will, contribute to infringement of the '502 patent immediately and imminently upon approval of the MSN ANDA.

98. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '502 patent.

99. Plaintiffs have no adequate remedy at law.

100. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

**COUNT VI**
**(Declaratory Judgment of Infringement of the '502 Patent)**

101. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

102. There is a substantial and immediate controversy between Plaintiffs and MSN concerning the '502 patent. Plaintiffs are entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that MSN will infringe, actively induce infringement of, and/or contribute to the infringement of the '502 patent upon approval of the MSN ANDA.

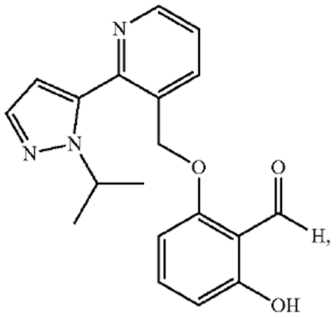
103. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '502 patent would infringe one or more claims of the '502 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

104. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '502 patent would induce and/or contribute to the infringement of one or more claims of the '502 patent under 35 U.S.C. §§ 271(b) and/or (c).

105. For example, claim 1 of the '502 patent recites:

A composition comprising a crystalline ansolvate of Compound 1:

Compound 1



characterized by X-ray powder diffraction peaks (Cu Kα radiation) at 13.37°, 14.37°, 19.95° and 23.92° 2θ (each ±0.2° 2θ), wherein the composition is substantially free of other ansolvate polymorphs of Compound 1.

106. Upon information and belief, MSN's ANDA Product will contain a composition comprising a crystalline ansolvate of Compound 1, characterized by X-ray powder diffraction peaks (Cu Kα radiation) at 13.37°, 14.37°, 19.95°, and 23.92° 2θ (each ±0.2° 2θ), wherein the composition is substantially free of other ansolvate polymorphs of Compound 1.

107. Upon information and belief, Defendants have acted with full knowledge of the '502 patent and without a reasonable basis for believing that they would not be liable for infringement of the '502 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product with its proposed labeling immediately and imminently upon approval of the MSN ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '502 patent.

108. Upon information and belief, if the FDA approves the MSN ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '502 patent, and will do so immediately and imminently upon approval.

109. Upon information and belief, Defendants know that MSN's ANDA Product is especially made or adapted for use in infringing the '502 patent, and that MSN's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief,

Defendants plan and intend to, and will, contribute to infringement of the '502 patent immediately and imminently upon approval of the MSN ANDA.

110. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '502 patent.

111. Plaintiffs have no adequate remedy at law.

112. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

113. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of MSN's ANDA Product with its proposed labeling will infringe the '502 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

**COUNT VII**
**(Infringement of the '382 Patent)**

114. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

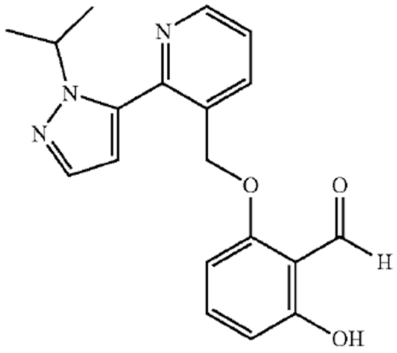
115. Defendants have infringed one or more claims of the '382 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining the MSN ANDA, by which Defendants seek approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of MSN's ANDA Product before the expiration of the '382 patent.

116. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '382 patent would infringe one or more claims of the '382 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

117. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '382 patent would induce and/or

contribute to the infringement of one or more claims of the '382 patent under 35 U.S.C. §§ 271(b) and/or (c).

118. For example, claim 1 of the '382 patent recites:

> A method for treating sickle cell disease in a human patient in need thereof comprising administering to the patient Compound 1:
>
> 1
>
> 
> 
>
> wherein Compound 1 is administered orally in a dose of about 1500 mg once daily; and Compound 1 is in a crystalline ansolvate form characterized by X-ray powder diffraction peaks (Cu Kα radiation) at 13.37°, 14.37°, 19.95° and 23.92° 2θ, each peak is ± 0.2° 2θ.

119. Upon information and belief, following FDA approval of the MSN ANDA, MSN's ANDA Product will be used in a method for treating sickle cell disease in a human patient in need thereof comprising administering to the patient Compound 1. Upon further information and belief, Compound 1 of MSN's ANDA Product will be administered orally in a dose of about 1500 mg once daily, and Compound 1 is in a crystalline ansolvate form characterized by X-ray powder diffraction peaks (Cu Kα radiation) at 13.37°, 14.37°, 19.95°, and 23.92° 2θ, each peak is ± 0.2° 2θ.

120. Upon information and belief, Defendants have acted with full knowledge of the '382 patent and without a reasonable basis for believing that they would not be liable for infringement of the '382 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product with its proposed

labeling immediately and imminently upon approval of the MSN ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '382 patent.

121. Upon information and belief, if the FDA approves the MSN ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '382 patent, and will do so immediately and imminently upon approval.

122. Upon information and belief, Defendants know that MSN's ANDA Product is especially made or adapted for use in infringing the '382 patent, and that MSN's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '382 patent immediately and imminently upon approval of the MSN ANDA.

123. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '382 patent.

124. Plaintiffs have no adequate remedy at law.

125. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

**COUNT VIII**
**(Declaratory Judgment of Infringement of the '382 Patent)**

126. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

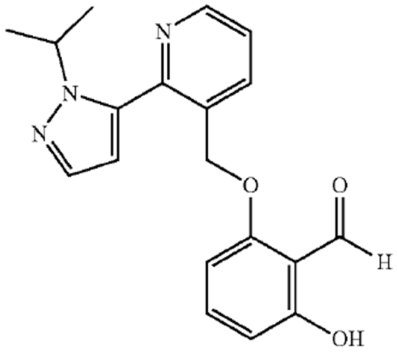
127. There is a substantial and immediate controversy between Plaintiffs and MSN concerning the '382 patent. Plaintiffs are entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that MSN will infringe, actively induce infringement of, and/or contribute to the infringement of the '382 patent upon approval of the MSN ANDA.

128. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '382 patent would infringe one

or more claims of the '382 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

129. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '382 patent would induce and/or contribute to the infringement of one or more claims of the '382 patent under 35 U.S.C. §§ 271(b) and/or (c).

130. For example, claim 1 of the '382 patent recites:

> A method for treating sickle cell disease in a human patient in need thereof comprising administering to the patient Compound 1:
>
> 1
>
> 
> 
>
> wherein Compound 1 is administered orally in a dose of about 1500 mg once daily; and Compound 1 is in a crystalline ansolvate form characterized by X-ray powder diffraction peaks (Cu Kα radiation) at 13.37°, 14.37°, 19.95° and 23.92° 2θ, each peak is ± 0.2° 2θ.

131. Upon information and belief, following FDA approval of the MSN ANDA, MSN's ANDA Product will be used in a method for treating sickle cell disease in a human patient in need thereof comprising administering to the patient Compound 1. Upon further information and belief, Compound 1 of MSN's ANDA Product will be administered orally in a dose of about 1500 mg once daily, and Compound 1 is in a crystalline ansolvate form characterized by X-ray powder diffraction peaks (Cu Kα radiation) at 13.37°, 14.37°, 19.95°, and 23.92° 2θ, each peak is ± 0.2° 2θ.

132. Upon information and belief, Defendants have acted with full knowledge of the '382 patent and without a reasonable basis for believing that they would not be liable for infringement of the '382 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product with its proposed labeling immediately and imminently upon approval of the MSN ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '382 patent.

133. Upon information and belief, if the FDA approves the MSN ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '382 patent, and will do so immediately and imminently upon approval.

134. Upon information and belief, Defendants know that MSN's ANDA Product is especially made or adapted for use in infringing the '382 patent, and that MSN's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '382 patent immediately and imminently upon approval of the MSN ANDA.

135. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '382 patent.

136. Plaintiffs have no adequate remedy at law.

137. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

138. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of MSN's ANDA Product with its proposed labeling will infringe the '382 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

**COUNT IX**
**(Infringement of the '720 Patent)**

139. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

140. Defendants have infringed one or more claims of the '720 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining the MSN ANDA, by which Defendants seek approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of MSN's ANDA Product before the expiration of the '720 patent.

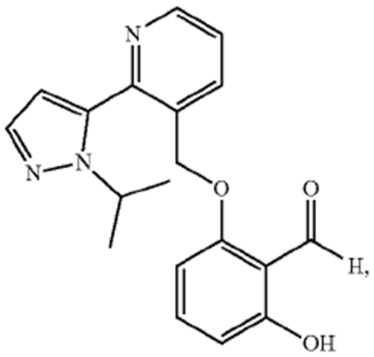
141. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '720 patent would infringe one or more claims of the '720 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

142. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '720 patent would induce and/or contribute to the infringement of one or more claims of the '720 patent under 35 U.S.C. §§ 271(b) and/or (c).

143. For example, claim 1 of the '720 patent recites:

> A method for treating sickle cell disease, comprising administering to a patient in need thereof:
> a composition comprising a crystalline ansolvate of Compound 1:

Compound 1



characterized by X-ray powder diffraction peaks (Cu Kα radiation) at 13.37°, 14.37°, 19.95° and 23.92° 2θ (each ±0.2° 2θ), wherein the composition is substantially free of other ansolvate polymorphs of Compound 1; and another active agent.

144. Upon information and belief, following FDA approval of the MSN ANDA, MSN's ANDA Product will be used in a method for treating sickle cell disease, comprising administering to a patient in need thereof a composition comprising a crystalline ansolvate of Compound 1, and another active agent. On further information and belief, the composition of MSN's ANDA Product comprising a crystalline ansolvate of Compound 1 will be characterized by X-ray powder diffraction peaks (Cu Kα radiation) at 13.37°, 14.37°, 19.95°, and 23.92° 2θ (each ±0.2° 2θ), wherein the composition is substantially free of other ansolvate polymorphs of Compound 1.

145. Upon information and belief, Defendants have acted with full knowledge of the '720 patent and without a reasonable basis for believing that they would not be liable for infringement of the '720 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product with its proposed labeling immediately and imminently upon approval of the MSN ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '720 patent.

146. Upon information and belief, if the FDA approves the MSN ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '720 patent, and will do so immediately and imminently upon approval.

147. Upon information and belief, Defendants know that MSN's ANDA Product is especially made or adapted for use in infringing the '720 patent, and that MSN's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief,

Defendants plan and intend to, and will, contribute to infringement of the '720 patent immediately and imminently upon approval of the MSN ANDA.

148. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '720 patent.

149. Plaintiffs have no adequate remedy at law.

150. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

**COUNT X**
**(Declaratory Judgment of Infringement of the '720 Patent)**

151. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

152. There is a substantial and immediate controversy between Plaintiffs and MSN concerning the '720 patent. Plaintiffs are entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that MSN will infringe, actively induce infringement of, and/or contribute to the infringement of the '720 patent upon approval of the MSN ANDA.

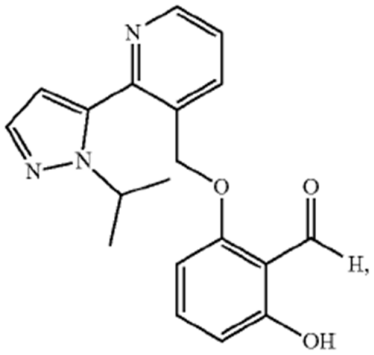
153. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '720 patent would infringe one or more claims of the '720 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

154. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of MSN's ANDA Product within the United States, or importation of MSN's ANDA Product into the United States, during the term of the '720 patent would induce and/or contribute to the infringement of one or more claims of the '720 patent under 35 U.S.C. §§ 271(b) and/or (c).

155. For example, claim 1 of the '720 patent recites:

A method for treating sickle cell disease, comprising administering to a patient in need thereof:
a composition comprising a crystalline ansolvate of Compound 1:

Compound 1




characterized by X-ray powder diffraction peaks (Cu Kα radiation) at 13.37°, 14.37°, 19.95° and 23.92° 2θ (each ±0.2° 2θ), wherein the composition is substantially free of other ansolvate polymorphs of Compound 1; and
another active agent.

156. Upon information and belief, following FDA approval of the MSN ANDA, MSN's ANDA Product will be used in a method for treating sickle cell disease, comprising administering to a patient in need thereof a composition comprising a crystalline ansolvate of Compound 1, and another active agent. On further information and belief, the composition of MSN's ANDA Product comprising a crystalline ansolvate of Compound 1 will be characterized by X-ray powder diffraction peaks (Cu Kα radiation) at 13.37°, 14.37°, 19.95°, and 23.92° 2θ (each ±0.2° 2θ), wherein the composition is substantially free of other ansolvate polymorphs of Compound 1.

157. Upon information and belief, Defendants have acted with full knowledge of the '720 patent and without a reasonable basis for believing that they would not be liable for infringement of the '720 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of MSN's ANDA Product with its proposed labeling immediately and imminently upon approval of the MSN ANDA. Upon information

and belief, through such activities, Defendants specifically intend infringement of the '720 patent.

158. Upon information and belief, if the FDA approves the MSN ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '720 patent, and will do so immediately and imminently upon approval.

159. Upon information and belief, Defendants know that MSN's ANDA Product is especially made or adapted for use in infringing the '720 patent, and that MSN's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '720 patent immediately and imminently upon approval of the MSN ANDA.

160. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '720 patent.

161. Plaintiffs have no adequate remedy at law.

162. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

163. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of MSN's ANDA Product with its proposed labeling will infringe the '720 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

164. The factual contentions in the preceding paragraphs have evidentiary support, or likely will have evidentiary support after a reasonable opportunity for further investigation or discovery.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Defendants and respectfully request the following relief:

A. A judgment that Defendants have infringed the patents-in-suit pursuant to 35 U.S.C. § 271(e)(2)(A) by submitting to the FDA and maintaining ANDA No. 219094;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of approval of ANDA No. 219094 shall be a date not earlier than the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

C. A judgment declaring that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of MSN's ANDA Product will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants, their officers, agents, servants, and employees, and those persons acting in privity or concert with them, from manufacturing, using, offering to sell, or selling MSN's ANDA Product within the United States, or importing MSN's ANDA Product into the United States, before the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

E. If Defendants commercially manufacture, use, offer to sell, or sell the MSN's ANDA Product within the United States, or import MSN's ANDA Product into the United States, before the expiration of the patents-in-suit, including any extensions, a judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

F. A judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Plaintiffs their attorneys' fees incurred in this action;

G. A judgment awarding Plaintiffs costs and expenses incurred in this action; and Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Megan E. Dellinger*

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